Supreme Court, U.S.
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No.

In the Supreme Court of the United States

EXCEL CORPORATION,

Petitioner,

v.

ESTATE OF BRIANNA L. KRIEFALL, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

PETITION FOR A WRIT OF CERTIORARI

RALPH A. WEBER
AMELIA L. MCCARTHY
SHAWN K. STEVENS
Reinhart Boerner Van Deuren S.C.
1000 North Water Street
P.O. Box 2965
Milwaukee, WI 53201
(414) 298-1000

ANDREW J. PINCUS
Counsel of Record
RICHARD B. KATSKEE
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Petitioner

115 pp

QUESTION PRESENTED

The Federal Meat Inspection Act, 21 U.S.C. §§ 601-695, mandates comprehensive federal inspection of meat products, slaughtering facilities, and processing plants, and prohibits the shipment in commerce of meat that is "adulterated." 21 U.S.C. § 610(c). The Secretary of Agriculture has issued an interpretive rule stating that steaks, roasts, and other intact meats bearing the bacteria *E. coli* O157:H7 are not adulterated, because the bacteria are rendered harmless with ordinary cooking. The Wisconsin Court of Appeals held that it could not consider the Secretary's views in interpreting the statutory language, and concluded that such meat is adulterated within the meaning of the statute, invalidating the Secretary's administrative interpretation and subjecting meat processors to potential civil and criminal liability under state law for observing that federal standard.

The question presented is:

Whether the Federal Meat Inspection Act precludes the Secretary from issuing rules interpreting the key statutory term "adulterated," bars courts construing that term from giving any weight to the Secretary's interpretation, and therefore compels a construction of "adulterated" different from the Secretary's that subjects meat processors to conflicting standards.

PARTIES TO THE PROCEEDING

The petitioner is Excel Corporation.

The parties to the consolidated proceeding in the trial court were: as, plaintiffs, Estate of Brianna L. Kriefall, Douglas A. Kriefall, Connie J. Kriefall, Chad Kriefall, Ervin J. Lesak, Florence Lesak, Jeffrey Fortier, Judith Fortier, Tristan Fortier, Carly Fortier, Kevin McCormick, Sandy McCormick, and Kelsea McCormick; as "involuntary plaintiffs," Humana/Employers Health Insurance Company, Great West Life & Annuity Insurance, and Blue Cross Blue Shield United; as defendant and third-party plaintiff, Sizzler USA Franchise, Inc.; as defendants, Federal Insurance Co., E&B Management Co. Waukesha, Inc., Secura Insurance, SYSCO Services of Eastern Wisconsin, Excel Corporation, Fidelity and Guaranty Insurance Co., and American Home Assurance Co.; as defendants and third-party defendants, Lee M. Eschenbach, Steven C. Boysa, AAA Insurance Co., and BBB Insurance Co.; and, as third-party defendants, Cargill, Inc., and Excel Food Distribution, Inc.

RULE 29.6 STATEMENT

Petitioner Excel Corporation is a wholly-owned subsidiary of Cargill Incorporated, a privately-owned company.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the Wisconsin Court of Appeals (App., *infra*, 1a) is reported at 665 N.W.2d 417. The opinion of the Milwaukee County Circuit Court (App., *infra*, 48a) is unreported.

JURISDICTION

The judgment of the Court of Appeals of Wisconsin was entered on May 13, 2003. Petitioner filed a timely petition for review in the Supreme Court of Wisconsin on June 12, 2003. The petition was denied on September 12, 2003. App., *infra*, 44a. The jurisdiction of this Court rests on 28 U.S.C. § 1257(a).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695, are reproduced in the appendix to this petition at 55a-60a.

STATEMENT

Congress enacted the Federal Meat Inspection Act ("FMIA" or "Act"), 21 U.S.C. §§ 601-695, in order to protect and promote national markets for "wholesome, not adulterated, and properly labeled and packaged meat," and thereby to ensure that meat entering commerce is fit for human consumption. 21 U.S.C. § 602. The Act expressly preempts state requirements "in addition to, or different than" those issued by the Secretary of Agriculture, allowing the States to exercise "concurrent jurisdiction" only with respect to meat that is "adulterated" and therefore unlawful to ship in commerce. *Id.* § 678. The extensive federal regulatory regime — and the area of exclusive federal authority — thus turn upon the distinction between "adulterated" and "unadulterated" meat.

Exercising her general rulemaking authority under the FMIA, the Secretary determined that *intact* meats, such as steaks or roasts, are not "adulterated" if they bear *E. coli* O157:H7 ("*E. coli*") bacteria on their surface, and that these meats may therefore be shipped and sold in commerce, because the bacteria are rendered harmless with ordinary cooking. By contrast, the Secretary has declared *E. coli* to be an adulterant in *ground* meat because it can be more difficult to kill the bacteria that the grinding process may introduce into the meat's interior.

The plaintiffs in these consolidated tort actions became ill after eating items from a salad bar that, according to the Wisconsin Department of Health, had been contaminated with *E. coli* when food was mishandled by a restaurant where plaintiffs dined. They seek to hold petitioner liable for having produced and shipped raw, intact meat that ultimately was resold to the restaurant, alleging that this meat was the original source of the *E. coli* bacteria. The trial court dismissed those claims, finding them to be barred by the FMIA's express preemption provision, while allowing plaintiffs to proceed against the restaurant and its franchisor based upon the mishandling of the food.

The Wisconsin Court of Appeals reversed the dismissal. Concluding that the Secretary of Agriculture lacks authority under the FMIA to interpret the statutory term "adulterated" — notwithstanding the FMIA's express grant of general rulemaking authority (21 U.S.C. § 621) — the court deemed irrelevant the Secretary's determinations regarding whether and when *E. coli* presents a health risk that might render it an adulterant. The court adopted its own interpretation of the term "adulterated," branding any meat product, intact or otherwise, as "adulterated" if it bears even the slightest trace of *E. coli* — *whether or not proper handling and cooking would negate any health risks for those who consume the meat.* The court then

reasoned that, because the FMIA prohibits the sale of "adulterated" meat, tort liability for the sale of such meat is not a preempted additional or different state law requirement but instead falls within the scope of Wisconsin's "concurrent jurisdiction" under the Act. 21 U.S.C. § 678.

The court's decision stripping the Secretary of the general rulemaking authority conferred on her by the FMIA, declining to consider her determinations about when meat is potentially injurious to health, and substituting the court's mechanical and illogical view of the meaning of "adulterated" cannot be reconciled with the plain language of the FMIA or this Court's precedents. Moreover, it conflicts with decisions of several other appellate courts.

Most importantly, the decision below significantly undermines an important regulatory system. It undercuts the Secretary's authority to determine when and how to protect consumers, destroys the national uniformity that Congress mandated and creates intolerable uncertainty for meat processors — who may face criminal and civil liability for processing meat in reliance on USDA standards if, as in this case, courts are free to deem the Secretary's determinations irrelevant and to impose their own idiosyncratic interpretations of the Act. Review of the Wisconsin Court of Appeals' decision is therefore clearly warranted.

A. The Federal Meat Inspection Act

1. *The Regulatory System.* Congress found that uniform federal regulation of meat is necessary both to protect and to promote national markets for "wholesome, not adulterated, and properly labeled and packaged meat," and thereby to prevent "sundry losses to livestock producers and processors of meat" as well as injuries to consumers. 21 U.S.C. § 602. Accordingly, it enacted the FMIA, "establish[ing] sanitary standards for slaughter and processing establishments, and

mandat[ing] antemortem inspection of animals * * * and postmortem inspection of every carcass," as well as requiring continuing inspection of each meat item until it is packaged and sealed for shipment. 60 Fed. Reg. 6774, 6775 (Feb. 3, 1995). *See generally* 21 U.S.C. §§ 603-610, 612-613, 615. All of these requirements are designed to ensure that meat products distributed in commerce are "wholesome, not adulterated, and properly marked, labeled, and packaged." *Id.* § 602.

The Act contains a detailed definition of "adulterated" — the statutory term at the center of this case — that includes both specific elements and more general ones (*see* 21 U.S.C. § 601(m)). Generally, meat is adulterated

> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health; [or]
>
> (2)(A) if it bears or contains * * * any added poisonous or added deleterious substance * * * which may, in the judgment of the Secretary, make such article unfit for human food * * *.

Id. § 601(m)(1)-(2)(A).

The statute aims to prevent the shipment in commerce of "adulterated" meat through two means: an extraordinarily comprehensive federal inspection program and the imposition of civil and criminal penalties on any person who places adulterated meat into commerce.

First, the FMIA authorizes the Secretary to "prescribe the rules and regulations of sanitation under which [meat processing] establishments shall be maintained" (21 U.S.C.

§ 608) and requires government inspection of every such establishment, every carcass, and every meat product (*id.* §§ 603-607). Accordingly, the Food Safety and Inspection Service ("FSIS") of the Department of Agriculture[1] stations federal inspectors in every "official establishment" that slaughters and processes meats for shipment in commerce in order to ensure that the meats produced there are wholesome, unadulterated, and therefore fit for human consumption. 60 Fed. Reg. at 6775.

FSIS inspectors work shoulder-to-shoulder with plant employees and directly supervise every facet of the meat production process, including, among other things, approving plant construction and maintenance, equipment, hours of operation, employee hygiene, manufacturing processes, and speed of production lines. *See, e.g.*, 9 C.F.R. §§ 307.1-.5, 310.1, 416.2-.6; 61 Fed. Reg. 38,806, 38,855 (July 25, 1996). FSIS inspectors also perform an "organoleptic" examination (*i.e.*, one employing the senses of sight, touch, and smell) on *every* live animal before slaughter and *every* carcass after slaughter to screen out diseased animals; and they carefully monitor slaughtering and processing facilities, and every meat product passing through them, to ensure proper sanitation and to prevent the use of dangerous preservatives. 60 Fed. Reg. at 6775-77.

When plant conditions "are such that the meat or meat food products are rendered adulterated," the Secretary "shall refuse" to label meat as having passed federal inspection. 21 U.S.C. § 608. The statute prohibits the shipment and sale of any meats that fail federal inspection (*id.* § 610), and authorizes the Secretary to bring civil and criminal actions for violations of the Act or USDA regulations (*id.* §§ 671-676 (authorizing

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[1] The Secretary has delegated her statutory authority to the FSIS. *See* 7 C.F.R. § 2.53(a)(2)(ii).

withdrawal of inspection; administrative detention, seizure, and condemnation of adulterated or misbranded meats; actions for injunctive relief; and other civil and criminal penalties)). If a plant produces adulterated meat, the FSIS inspectors may act immediately and without notice to require corrective action or to withhold or suspend federal inspection — thus shutting down the facility. *See* 9 C.F.R. § 500.1-.3.

Second, wholly apart from the inspection requirement, the Act bars any person from selling or transporting "adulterated or misbranded" meat. 21 U.S.C. § 610(c)(1). It also prescribes both civil and criminal penalties for violations. *Id.* §§ 671-676.

Like many federal statutes, the Act endows the Secretary with broad authority to "make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter * * *." 21 U.S.C. § 621; *see also ibid.* (authorizing the Secretary to perform the duties "provided by this chapter and by the rules and regulations to be prescribed by said Secretary").

In the 1990s, FSIS exercised this rulemaking authority to require each federally-inspected facility to conduct a "hazard analysis" to "determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards." 9 C.F.R. § 417.2(a). Each facility must prepare a written Hazard Analysis and Critical Control Point ("HACCP") plan for approval by FSIS. *Id.* §§ 417.2-.3, 417.8.

The purpose of the plan is to further the goal of the federal Act — to "control food safety hazards and prevent the distribution of adulterated livestock products." 63 Fed. Reg. 11,104, 11,105 (Mar. 6, 1998); *see also* 9 C.F.R. § 417.6(e).

Once the agency approves a plan, it applies with the same force as all other USDA regulations, and FSIS verifies and

enforces compliance as part of its ongoing regulatory oversight of the facility. 9 C.F.R. § 417.8. HAACP thus added a new layer of mandatory federal regulation on top of FSIS's long-standing programs of organoleptic inspections and sanitation regulations. All three regulatory approaches are focused on the same goal — preventing distribution in commerce of adulterated meat.

2. *Preemption of State Law.* The FMIA also includes an express preemption clause prohibiting the States from imposing "[r]equirements * * * with respect to premises, facilities and operations of any establishment at which [federal] inspection is provided" that are "in addition to, or different than, those made under [the federal Act]." 21 U.S.C. § 678. This preemption clause also provides, however, that the States "may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected * * * for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of [a slaughtering or processing] establishment." *Ibid.*

Section 678 thus bars States from imposing their own requirements on meat production or processing, or on any aspect of the operation of a federally-inspected facility where such operations take place. However, meats shipped out of such a facility in an "adulterated" or "misbranded" condition are subject to state as well as federal law. States are free, for example, to impose civil and criminal penalties for the sale, distribution, or transportation of "adulterated" and "misbranded" meats; to condemn such meats; and to permit tort liability for injuries resulting from the consumption of such meats. *See, e.g., Armour & Co.* v. *Ball*, 468 F.2d 76, 84 (6th Cir. 1972) (states have authority under 21 U.S.C. § 678 to engage in "concurrent enforcement" with respect to adulterated or misbranded meats, but may not "prevent the distribution in

commerce of any article that 'conforms' to" USDA standards); *Kircos* v. *Holiday Food Ctr., Inc.*, 477 N.W.2d 130, 132 (Mich. Ct. App. 1991) (Michigan has "concurrent jurisdiction for the purposes of preventing the distribution of 'adulterated' food" but is preempted from imposing tort liability for meat not "adulterated" under USDA regulations); *Meat Trade Inst., Inc.* v. *McLaughlin*, 326 N.Y.S.2d 683, 685 (App. Div. 1971) (same); *see also Jones* v. *Rath Packing Co.*, 430 U.S. 519, 529-32 & n.18 (1977) (California may impose statistical sampling to enforce FMIA's net-weight labeling requirements, but only if the state program allows for weight variations permitted by USDA).

B. *E. Coli*-Related Illness And The Federal Response

Bacteria such as *E. coli* and various Salmonella strains naturally "exist in warm-blooded animals." *Food Safety and Government Regulation of Coliform Bacteria: Hearing Before the Subcomm. on Agric. Research, Conservation, Forestry, and Gen. Legis. of the Senate Comm. on Agric., Nutrition, and Forestry* ("*Food Safety Hearing*"), 103rd Cong. 33 (1993) (statement of Mike Espy, Sec'y of Agric.). Many of these bacteria are harmless, but some have the capacity to cause serious illnesses when ingested by humans "depending on the type of microorganism and the immune status of the person infected." 60 Fed. Reg. at 6780.

USDA has repeatedly explained that "proper cooking of meat and poultry products kill[s] harmful bacteria." *Food Safety Hearing*, *supra*, at 122 (statement of Dr. H. Russell Cross, Adm'r, FSIS, before State of Wash. Senate Comm. on Agric., Feb. 2, 1993), App., *infra*, 65a; *see also, e.g.*, 60 Fed. Reg. at 6799 ("proper cooking kills pathogens present on raw [meat]"); *American Pub. Health Ass'n* v. *Butz*, 511 F.2d 331, 332 (D.C. Cir. 1974).

For that reason, prior to 1994 USDA did not consider the presence of any bacteria sufficient to render any raw meat "adulterated." *Food Safety Hearing*, *supra*, at 122 (Cross statement), App., *infra*, 65a ("[meat] products inherently contain bacteria, which does not cause them to be adulterated under law"); *accord Butz*, 511 F.2d at 333.

The agency's approach changed, however, following a much-publicized incident in which several hundred people got sick and four individuals died from eating undercooked hamburgers containing *E. coli* at Jack in the Box restaurants. USDA recognized that this particular strain of bacterium gives rise to special concerns when present in ground beef:

> Ground beef is * * * greatly different from beef roasts and other so-called solid meats. It is potentially a more hazardous product because the grinding process mixes pathogens [*i.e.*, bacteria] normally found only on the surface of solid meats to a relative uniformity throughout the product. This means that adequate cooking must occur throughout the hamburger in order to kill all the pathogens.

Food Safety Hearing, *supra*, at 49 (statement of Dr. Douglas L. Archer, Deputy Dir. for Programs, Ctr. for Food Safety & Applied Nutrition, FDA); *see also* 64 Fed. Reg. 2803, 2803 (Jan. 19, 1999).

Accordingly, in 1994, USDA imposed two new requirements. First, it began mandating labels on all raw meats to warn of the need for proper handling and cooking in order to prevent bacteria-related illnesses. 59 Fed. Reg. 14,528 (Mar. 28, 1994) (codified at 9 C.F.R. § 317.2(l)).

Second, it issued an interpretive rule declaring ground beef to be "adulterated" if it contains *E. coli*, as well as an accompanying procedural rule providing for testing of random

samples of ground beef to determine whether that strain of *E. coli* is present. *See* 67 Fed. Reg. 62,325, 62,326 (Oct. 7, 2002); *Texas Food Indus. Ass'n* v. *Espy*, 870 F. Supp. 143, 145-49 (W.D. Tex. 1994) (denying preliminary injunction to prevent enforcement of interpretive rule that *E. coli* is an adulterant in ground beef).

This rule distinguishes intact meats from ground meat. Because "[i]ntact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed," USDA concluded that the presence of *E. coli* (or other bacteria) on the surface of intact meat does not render the meat "adulterated." 64 Fed. Reg. at 2804; *see also* 67 Fed. Reg. at 62,326.

The Secretary developed these rules based upon agency experience and expertise in this area, and has recently reaffirmed their validity in light of extensive data — including results from FSIS's ongoing *E. coli* testing in meat processing facilities, as well as peer-reviewed studies and other scientific evidence issuing from the Centers for Disease Prevention and Control, USDA's Agricultural Research Service, and FSIS's National Advisory Committee on Microbiological Criteria for Foods. *See* 67 Fed. Reg. at 62,325-62,334.[2]

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[2] The determination that *E. coli* is not an adulterant for intact meat notwithstanding, FSIS still seeks removal of potential sources of pathogens such as visible ingesta and fecal matter (which can be transferred from cattle's digestive tracts or hides to the carcasses) from all meat products, whether they are destined to be served as ground meat or intact cuts. *See* 9 C.F.R. § 310.18. Indeed, during the past decade, the Secretary has moved to a "zero tolerance" system with respect to such identifiable contaminants on meat. *See* FSIS Directive 6420.1 (Dec. 17, 1998), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6420-1.pdf.

C. Respondents' Lawsuit And The Trial Court's Grant Of Summary Judgment In Favor Of Excel

Petitioner Excel Corporation sold intact cuts of raw sirloin to Sysco Services of Eastern Wisconsin, which in turn resold them to its customer E&B Management Co. Waukesha, Inc., for use as steaks at E&B's Sizzler restaurant franchises in Milwaukee, Wisconsin. *See* App., *infra*, 10a-11a. Before leaving Excel's slaughter and processing facility in Fort Morgan, Colorado, the meat passed USDA inspection to ensure that it was wholesome and not adulterated, and that it therefore could lawfully be shipped and sold for human consumption. *See ibid.* "The meat sold by Excel arrived at the Sizzler restaurant as wrapped intact cuts of beef that bore labels warning the Sizzler employees to cook the meat thoroughly, to keep the raw meat away from other foods, and to wash working surfaces, tools, utensils, and hands after their contact with raw meat." *See id.* at 17a.

In July 2000, the salad bar at E&B's Sizzler franchise became cross-contaminated with *E. coli*. Br. & App. of Def.-Resp't Excel Corp. in Wisconsin Court of Appeals at App. 18. After eating the cross-contaminated food, a number of Sizzler patrons became ill; and a child, Brianna Kriefall, died. The Sizzler patrons brought these common law tort actions in the Circuit Court for Milwaukee County against a variety of

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While imposing these increasingly rigorous standards with respect to possible sources of bacteria, however, the Secretary has consistently recognized that "[f]ecal contamination * * * does not always correlate with the presence of pathogens." 61 Fed. Reg. at 38,850; *see also* 60 Fed. Reg. at 6780 ("Removing visible fecal contamination is important, but it does not assure the absence of harmful bacteria that cannot be detected visually."). And the Secretary has adhered to her view that intact meat bearing *E. coli* is not adulterated.

defendants, including E&B, Sizzler USA Franchise, Inc. (E&B's franchisor), Sysco (E&B's distributor), Excel, and their respective insurers.

Excel filed a motion for summary judgment, which the trial court granted. App., *infra*, 52a. The court first recognized that Congress has delegated to USDA the authority to "determine when meat is 'safe, wholesome, and not adulterated.'" App., *infra*, 48a-49a (quoting *Ball*, 468 F.2d at 81). The court then reviewed USDA regulations and interpretive rules, and determined that "[i]ntact meat containing surface *E. coli* O157:H7 bacteria is not considered adulterated under federal law because the bacteria is destroyed when the surface of the intact cuts are broiled in establishments like Sizzler's Steak House." *Id.* at 49a (citing 64 Fed. Reg. at 2804).

Relying on *Boulahanis* v. *Prevo's Family Market, Inc.*, 583 N.W.2d 509 (Mich. Ct. App. 1998), which held state tort claims preempted by USDA's pre-1994 decision not to classify *E. coli* as an adulterant in ground beef, the trial court concluded (without making any findings as to whether meat from Excel was the source of the bacteria here) that the plaintiffs' and franchisor's claims against Excel are barred by the FMIA's express preemption clause. App., *infra*, 49a (quoting 21 U.S.C. § 678).

The trial court explained that "[t]he policy behind preemption in this area makes sense." App., *infra*, 49a. It observed that the federal government has established uniform national standards so that properly handled and cooked meat products are safe for human consumption, and so that meat processors know what standards they must satisfy in order to distribute their products. The court concluded that "[t]he federal regulatory scheme * * * preempts any state laws to the contrary. That includes bringing civil suits against meat processors like Excel." *Id.* at 50a.

At the same time, the court noted that federal preemption of the claims against Excel "does not deny these plaintiffs their day in court" because "[t]hey may continue to proceed against the restaurant whose employees handled the food as well as against the restaurant's national franchisor, who is alleged to have improperly trained and supervised it[s] local franchisee." App., *infra*, 50a.

D. The Wisconsin Court Of Appeals' Decision

The Wisconsin Court of Appeals reversed the trial court's grant of summary judgment. App., *infra*, 36a. It held that the Secretary has no statutory authority to interpret the term "adulterated" under the FMIA, and therefore USDA may not prescribe whether or under what circumstances *E. coli* constitutes an adulterant for raw meat.

The court observed that the statutory definition of "adulterated" refers to the Secretary in only one of its nine paragraphs and concluded that the Secretary's interpretative authority was restricted to that one situation: "although Congress has in 21 U.S.C. § 601(m)(2)(A) delegated to the Secretary the responsibility to make a 'judgment' whether 'any . . . added deleterious substance' makes the meat to which the substance is added 'unfit for human food,' Congress has itself, in 21 U.S.C. § 601(m)(1), (3), & (4), defined 'adulterated' without seeking the Secretary's input." App., *infra*, 19a (omission in original).

Thus, reading the statute as prohibiting consideration of the Secretary's views, the court deemed irrelevant USDA's determinations that "'intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products'" and that *E. coli* on the surface of raw intact meat does not render the meat adulterated. *Id.* at 16a (quoting 64 Fed. Reg. at 2804). The court accordingly decided for itself that the presence of *E. coli*

bacteria renders intact meat adulterated under the FMIA. *Id.* at 19a-27a. Because in its view intact meat with *E. coli* on the surface is "adulterated," the court went on to hold that tort liability for the sale of such meat is consistent with the requirements of the FMIA and therefore is not precluded by the Act's express preemption clause. *Id.* at 30a-32a.[3]

The court of appeals also considered whether the tort actions were nonetheless preempted by "the Act's meat-inspection provisions and the regulations promulgated thereunder." App., *infra*, 19a. It held that its conclusion that the meat was "adulterated" within the meaning of the statute precluded preemption on this basis: "a claim premised on damages resulting from the sale of 'adulterated' meat * * * 'merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law.'" *Id.* at 30a (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495 (1996)). Because, in the court's view, any tort damages would be imposed for conduct violative of federal law, it concluded that the preemption provision does not apply.

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[3] The court of appeals also stated that Excel was obligated by the HACCP regulations to consider the intended uses of its meat in designing its HACCP plan, and intimated that the meat involved in this case therefore should be classified as non-intact. App., *infra*, 17a-18a. As we have discussed (at pages 6-7, *supra*), however, the HACCP regulations require meat processors to adopt plans to control food safety hazards; they do not constitute the Secretary's construction of "adulterated." The Secretary's interpretation of that term with respect to *E. coli* states that "intact products that are to be distributed for consumption as intact cuts are not deemed adulterated" if they bear *E. coli* bacteria. 64 Fed. Reg. at 2804. The record is clear that the meat products produced by Excel that ended up at the E&B Sizzler restaurant were intact cuts of sirloin. App., *infra*, 10a, 17a. There is no evidence in this case that these intact cuts were converted to ground beef or other non-intact products at the E&B Sizzler, as the trial court found. App., *infra*, 49a.

The Wisconsin Supreme Court denied review without explanation on September 12, 2003. App., *infra*, 44a.

REASONS FOR GRANTING THE PETITION

The Wisconsin Court of Appeals held that it could not even consider the Secretary's views before adopting its own interpretation of the term "adulterated" — an interpretation that runs directly counter to the Secretary's long-standing construction that bacteria are not regarded as adulterants for raw meat if ordinary cooking renders them harmless.

The Wisconsin court's novel conclusions are inconsistent with the plain language of the FMIA and, if permitted to stand, will foster widespread confusion in the industry and among state and federal enforcement personnel about the proper application of the FMIA and the standards for determining whether meat is adulterated. This confusion will significantly undermine the efficacy of our national food-safety system.

Congress's purpose was to create a uniform system of federal regulation — based upon the expert decisions of the Secretary — to prevent the shipment and sale of adulterated meat. But under the approach of the decision below, it is the determinations of the Wisconsin court, not those of the Secretary, that would control the activities of meat processors throughout the Nation. Meat processors seeking to avoid civil and criminal liability could no longer rely upon the Secretary's determinations regarding the meaning of "adulterated" but would have to alter their activities to take account of the differing standards adopted by courts like the one below. Without a clear understanding of what meat is "adulterated," neither the meat industry nor federal and state enforcement personnel will know how to fulfill their legal duties.

It is essential that this Court intervene to assure that the lower state and federal courts give appropriate weight to the

expert determinations of the Secretary and apply the FMIA in the uniform and coherent manner that Congress intended. Review by this Court is plainly warranted.[4]

I. THE WISCONSIN COURT OF APPEALS' DECISION IS STARKLY INCONSISTENT WITH THE FMIA'S PLAIN LANGUAGE AND THIS COURT'S PRECEDENTS.

The judgment below rests entirely on the court of appeals' surprising conclusion that the Secretary of Agriculture has no legal authority to interpret the key statutory term "adulterated." App., *infra*, 19a. Reading the statutory definition of that term as a congressional prohibition against giving any weight to the Secretary's interpretation, the court entirely ignored USDA's determinations about the actual health risks of *E. coli* O157:H7, deciding, contrary to the agency, that the presence of surface *E. coli* renders intact meat "adulterated" under the FMIA. *Id.* at 13a-14a. The court then reversed the trial judge's finding of

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[4] The lower court's judgment is "[f]inal" within the meaning of 28 U.S.C. § 1257. The federal issue of whether the Secretary of Agriculture has the authority to interpret the statutory term "adulterated," and thus whether common-law tort actions are preempted by the Secretary's determination that the type of meat at issue may lawfully be shipped in commerce, "has been finally decided in the state courts with further proceedings pending in which [Excel] might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court." *Cox Broad. Corp.* v. *Cohn*, 420 U.S. 469, 482 (1975). Moreover, "reversal of the state court on the federal issue would be preclusive of any further litigation" because, in that case, the state-law cause of action against Excel would be preempted. *Id.* at 482-83. And, as we will show below, a "a refusal immediately to review the state court decision might seriously erode [the] federal policy" of establishing and enforcing uniform national standards for wholesomeness and safety of meats shipped in interstate commerce. *Id.* at 483.

federal preemption because the statute does not preempt tort claims with respect to "adulterated" meat. *Id.* at 29a-30a.

Each link in the chain of inferences that the court used to strip the Secretary of her rulemaking authority and adopt its rigid and illogical interpretation of the statute is irreconcilable with the plain language of the FMIA, violates well-settled canons of statutory construction, and defeats the legislative purposes underlying the Act.

1. The term "adulterated" delineates one of the most critical dividing lines established by the FMIA. It separates meat that may be distributed in commerce from meat that may not. And it identifies meat whose distribution may subject meat processors to the States' "concurrent jurisdiction" — including civil and criminal penalties and tort liability.

Yet the statutory definition of "adulterated" itself contains a number of terms that are far from clear. For example, Congress did not endeavor to define the term "injurious to health" in the definition of "adulterated." Nor, for that matter, did it specify what constitutes a "filthy, putrid, or decomposed substance," "insanitary conditions," or removal of a "valuable constituent" — though it generally identified all of these as circumstances rendering meat adulterated. 21 U.S.C. § 601(m)(3), (4), (8). "[T]he relatively unspecific nature of the * * * standard[s] which Congress has prescribed * * *, combined with the evident need for expert and technical judgment in applying [these] standard[s], suggests that this is an area in which courts must give great deference to the Secretary's judgments." *Community Nutrition Inst.* v. *Block*, 749 F.2d 50, 54 (D.C. Cir. 1984) (Scalia, J.); *cf. W.B. Wood Mfg. Co.* v. *United States*, 286 F. 84, 86 (7th Cir. 1923) ("Congress [did] not assume[] to define with absolute particularity what is or what is not injurious" in the FMIA's companion legislation, the Food and Drug Act of 1906, and the

meaning of the statutory term "deleterious ingredient, injurious to health" comes down to "a difference between chemists over the meaning of the words").

It is therefore entirely appropriate — indeed, absolutely necessary — for the Secretary to exercise her general rulemaking authority (21 U.S.C. § 621) to issue rules and regulations defining these terms and clarifying the standards that render meat adulterated if the purposes of the FMIA are to be achieved; and that is just what the Secretary has done. *See, e.g.*, 9 C.F.R. pt. 311. Meat processors simply could not comply with the statutory prohibition against shipping meat that is "adulterated or misbranded" (21 U.S.C. § 610(c)(1)) — on threat of civil and criminal penalties for a violation (*see id.* §§ 671-677) — without such guidance from the Secretary.

The court of appeals' conclusion that Congress intended to deprive the Secretary of any role in interpreting these aspects of the statutory definition of "adulterated," and that the Secretary's view therefore could not be given any weight, simply makes no sense.

This Court has consistently recognized Congress's power to make general delegations of rulemaking authority like the one in Section 621 of the FMIA — irrespective of whether the same statute also includes specific delegations. *See, e.g.*, *American Hosp. Ass'n* v. *NLRB*, 499 U.S. 606, 609-10 (1991); *SEC* v. *Jerry T. O'Brien, Inc.*, 467 U.S. 735, 745 (1984); *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 306 (1979); *Mourning* v. *Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973); *Thorpe* v. *Housing Auth.*, 393 U.S. 268, 280-81 (1969).

Congress's specific delegation of authority to the Secretary in Subsection 601(m)(1)(2)(A), a single clause of the nine-paragraph statutory definition of "adulterated," cannot reasonably be read to limit this general rulemaking authority. "Over and over [this Court has] stressed that '[i]n expounding

a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *United States Nat'l Bank of Oregon* v. *Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) (quoting *United States* v. *Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122 (1849)). The Wisconsin Court of Appeals' view that Subsection 601(m)(2)(A)'s reference to the Secretary's "judgment" constitutes a congressional prohibition against administrative rulemaking with respect to any other part of the statutory definition of "adulterated" — and a congressional mandate to disregard entirely the Secretary's expert judgments about what constitutes an adulterant — ignores this "central tenet of interpretation." *Lexecon, Inc.* v. *Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 36 (1998) ("a statute is to be considered in all its parts when construing any one of them"); *accord King* v. *St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991) (it is a "cardinal rule that a statute is to be read as a whole, since the meaning of statutory language, plain or not, depends on context") (citations omitted).[5]

2. Moreover, the Secretary's interpretation of the statute is much more consistent with the language and purpose of the statute than the rigid, illogical construction adopted by the court of appeals.

The FMIA generally defines meat as adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, [the meat] shall not be considered adulterated under this clause if the quantity of such substance in or on

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[5] Certainly the Wisconsin court was not entitled to ignore the Secretary's interpretation simply because it was embodied in an interpretive rule. Indeed, this Court recently rejected that view in *United States* v. *Mead*, 533 U.S. 218 (2001).

[meat] does not ordinarily render [the meat] injurious to health." *Id.* § 601(m)(1). In other words, the Act identifies meat as "adulterated" or not depending upon whether it will harm the health of those who eat it.

The specific conditions that Congress went on to identify as rendering meat adulterated are all to the same effect. Whether the concern is that the meat bears an "unsafe" pesticide or additive (21 U.S.C. § 601(m)(2)), that it consists of "filthy, putrid, or decomposed" substances (*id.* § 601(m)(3)), that it has been prepared under "insanitary conditions" (*id.* § 601(m)(4)), that it is "the product of an animal which has died otherwise than by slaughter" (*id.* § 601(m)(5)), that it is packed in a container that may impart a poisonous substance (*id.* § 601(m)(6)), that it has been subjected to harmful radiation (*id.* § 601(m)(7)), or that a "valuable constituent" has been removed or an inferior one substituted (*id.* § 601(m)(8)), the whole point of the statutory definition of "adulterated" is to ensure that the meat is fit to eat and not "injurious to health."

Consistent with this legislative purpose, the Secretary has declared *E. coli* to be an adulterant for ground meat and not one for intact meat only after determining, based on her expertise, that if each package is properly labeled to warn of the possibility of bacteria-related illnesses and the attendant need for safe handling (*see* 9 C.F.R. § 317.2(k)-(l)), the presence of surface *E. coli* on raw intact meat creates no health risks for those who eat the meat because the bacteria are killed with ordinary cooking. 67 Fed. Reg. at 62,326; 64 Fed. Reg. at 2804. In other words, the Secretary has concluded that *E. coli* does not "render" properly labeled raw intact meat "injurious to health" (21 U.S.C. § 601(m)(1)), and hence, such meat does not satisfy the statutory definition of "adulterated."

The Wisconsin Court of Appeals's contrary interpretation is so rigid that it simply makes no sense. Although recognizing

that meat bearing *E. coli* "can be rendered non-'injurious to health'" by the simple expedient of cooking it, the court nonetheless reasoned that this fact is irrelevant because Subsection 601(m)(1) defines "adulterated" to include meat bearing any substance that "may" render it injurious to health. App., *infra*, 14a. In the court's view, Congress's use of the word "may" means that any substance that "may" under any circumstance be "injurious to health" is an adulterant — irrespective of what the possible injury to health might be, how unlikely it is to occur, how easily it may be avoided, or what measures USDA or the meat processor might take to ensure that it will not come to pass.

All raw meat contains some bacteria — which is why meat spoils if it is not refrigerated. It therefore bears substances that "may" render it "injurious to health" if it is not properly handled and cooked. On the court of appeals' theory, all raw meat would accordingly be "adulterated" and unlawful to sell, and no federal inspector could ever inspect and pass any carcass as fit for human consumption because there would always be the possibility that it might injure someone's health. Surely that is not what Congress had in mind when it enacted the FMIA.

In sum, the decision below is clearly wrong. It rests on a fundamental misreading of both the plain statutory language and this Court's precedents.[6]

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[6] The court of appeals did not reach the question whether the FMIA preempts tort claims against processors concerning meat that the Act permits to be distributed in commerce, but the plain language of the statute makes clear that Congress intended for such claims to be preempted. *See* 21 U.S.C. § 678 (prohibiting imposition of any "[r]equirements within the scope of [the Act] * * * which are in addition to, or different than" those imposed by federal law, and affording States concurrent jurisdiction only over the distribution and

II. THE DECISION BELOW CREATES CONSIDERABLE UNCERTAINTY ABOUT THE STANDARDS GOVERNING MEAT PRODUCERS AND THREATENS TO DISRUPT THE FEDERAL REGULATORY SYSTEM.

The decision of the Wisconsin Court of Appeals will have significant repercussions that extend far beyond this case. By eliminating the Secretary's authority to construe key terms of the FMIA such as "adulterated" — and allowing courts, and presumably state regulators, to reach their own conclusions about the meaning of those terms — the decision below replaces the relative certainty and clarity of the current system with an ad hoc regime that, as in this case, would produce competing standards from the Secretary and the States. Meat processors trying to comply with multiple "rules" would be left to navigate the ensuing confusion, potentially subject to criminal and civil penalties as well as tort liability in the event that a court subsequently determined that they erroneously relied upon the Secretary's standards. Similarly, FSIS inspectors in plants across the Nation would no longer have one standard by which to determine which meat should be "inspected and passed" (*see* 21 U.S.C. §§ 604, 606, 608) under the Act.

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sale of "adulterated or misbranded" meat). If processors were subject to tort liability for unadulterated meat, they would have to modify their procedures in order to avoid that state-law liability — precisely the sort of state-law interference with the federal regime that Congress sought to preclude by enacting broad preemption language. *See CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality op.); *id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part). Not surprisingly, no appellate court other than the court below has permitted the imposition of tort liability in these circumstances.

If the Wisconsin Court of Appeals was correct in holding that it should not even consider USDA's rules, practices, and interpretive decisions, but must instead decide entirely for itself whether and when *E. coli* might be an adulterant — and the State may then impose the court's divergent view through tort liability, civil fines, or even stiff criminal penalties under the guise of enforcing the FMIA — a meat processor such as Excel may have no choice but to adhere to Wisconsin's standard for all of its products that ultimately will be sold or served in the State. But that result would undercut Congress's intent that the Secretary of Agriculture should be the one to make determinations about when meat is legal to ship and sell.

Because the market for meat is a national one (21 U.S.C. § 602), moreover, meat processors typically have no idea where their products will eventually be sold or served. The only way that they can avoid tort liability in Wisconsin — not to mention criminal prosecution in that State for shipping "adulterated" meat — may therefore be to regard the court of appeals' interpretation of the FMIA, and not USDA's, as the national standard and to conform *all* of their products to it.

What is more, other States may try to follow Wisconsin's lead and adopt their own interpretations of the statute based on their own views of the relevant scientific and public-health issues. The possibility of multiple, and potentially conflicting, standards is obvious.

Here, for example, USDA sent a letter to Excel reaffirming its view that intact meat bearing *E. coli* is *not* adulterated. App., *infra*, 62a. Under the court of appeals' decision, however, such meat *is* adulterated and may not lawfully be placed in commerce. If that decision is permitted to stand, Excel will be placed on the horns of a dilemma — follow the Secretary's determination and risk liability under state law, including possibly sanctions from state regulators, or follow the

court's approach and alter the processes at its plants (which would require USDA approval), potentially shifting resources away from the prevention of risks that the Secretary has identified as priorities.

Nor is USDA's *E. coli* rule the only standard implicated by the court of appeals' decision. If the Wisconsin court was correct in concluding that the Secretary lacks authority to determine whether and when *E. coli* is an adulterant, then the same argument might be made for various strains of Salmonella and also for trichinae spiralis — a parasite in fresh pork that causes the potentially-fatal disease trichinosis. Both of these substances are commonly found in raw meat; their potential to cause illness has long been known to consumers; and, like *E. coli* on intact meat, any dangers to health that they may pose are entirely eradicated through normal cooking. *See, e.g.*, 60 Fed. Reg. at 6799-80; *Butz*, 511 F.2d at 332; *Cheli* v. *Cudahy Bros.*, 255 N.W. 414 (Mich. 1934). Yet the Wisconsin court of appeals' interpretation of the statutory term "adulterated" might be viewed as compelling the conclusion that raw meat bearing any trace of Salmonella or trichinae is adulterated.

Moreover, on the Wisconsin court's reasoning, the Secretary of Agriculture would lack rulemaking authority not only with respect to substances such as *E. coli*, Salmonella, and trichinae, but also with regard to all of the other possible adulterants covered by the entire nine-paragraph statutory definition of "adulterated" — with the exception of the narrow range of determinations that Subsection 602(m)(2)(A) specifically commits to the Secretary's "judgment." And the same reasoning might be applied to deny or rigidly limit the Secretary's rulemaking authority under at least eight of the twelve paragraphs of the FMIA's definition of "misbranded." *Compare* 21 U.S.C. § 601(n)(10) (meat purporting to be for "special dietary uses" is "misbranded" unless its label includes information prescribed by the Secretary) *with id.* § 601(n)(1)-

(4), (6) (making no reference to USDA rules or regulations) *and id.* § 601(n)(5), (9), (11) (affording discretion to grant limited exceptions to labeling requirements but not specifically recognizing general rulemaking authority).

Accordingly, the Wisconsin court's decision does not just displace the Secretary's determination regarding when *E. coli* or similar substances constitute adulterants; it effectively nullifies substantial portions of the entire system of federal meat inspection, including the long-standing, carefully-wrought, and highly detailed USDA regulations concerning non-adulteration and proper labeling, branding, and packaging. *See, e.g.*, 9 C.F.R. pt. 311 (diseases and other conditions rendering meat adulterated); *id.* pt. 316 (marking requirements); *id.* pt. 317 (labeling requirements); *id.* pt. 319 (standards of identity and composition).

That means companies like Excel that do business nationwide face an intolerable choice. Either they must comply with federal regulations — as Excel undeniably did here — and run the risk of tort liability, fines, and even prison sentences whenever a court subsequently disagrees with USDA about what constitutes an adulterant or a misleading label — or else they must attempt to predict what future courts might find to constitute adulteration or misbranding — and run the risk of being found in violation of the FMIA for making their products and packaging conform to those courts' preferences. Clearly, that is not what Congress envisioned when it enacted Section 678 of the federal Act.

Even that is not the full extent of the problem, for the Wisconsin Court of Appeals' denial of the Secretary's regulatory authority could be read to undercut laws in addition to the FMIA. The Poultry Products Inspection Act ("Poultry Act"), 21 U.S.C. §§ 451-471, is modeled on the FMIA (*see* 60 Fed. Reg. at 6776) and incorporates almost verbatim the

FMIA's statement of congressional findings (*id.* § 451), its statutory definitions of "adulterated" and "misbranded" (*id.* § 453(g)-(h)), and its express preemption provision (*id.* § 467e). In accordance with the canon of statutory construction that "statutes *in pari materia* should be interpreted harmoniously" (*Sullivan* v. *Finkelstein*, 496 U.S. 617, 632 (1990) (Scalia, J., concurring in part); *see also Branch* v. *Smith*, 538 U.S. 254, 123 S. Ct. 1429, 1446 (2003)), the lower courts have already recognized that the FMIA and the Poultry Act should presumptively be interpreted the same way. *See, e.g.*, *Kenney v. Glickman*, 96 F.3d 1118, 1124-25 (8th Cir. 1996); *Butz*, 511 F.2d at 334-35. The Wisconsin court's decision thus threatens the Secretary's rulemaking authority under the Poultry Act, thereby defeating Congressional intent to create a uniform national system for preventing the shipment and sale of adulterated and misbranded poultry. *See* 21 U.S.C. §§ 451-452, 467(e).

This Court should grant review to prevent the significant disruption of our national food-safety system that is an inevitable consequence of the court of appeals' ruling.

III. THE DECISION BELOW CLEARLY CONFLICTS WITH DECISIONS OF FEDERAL AND STATE APPELLATE COURTS.

The decision below creates several clear conflicts among the state and federal appellate courts with respect to important provisions of the FMIA. Congress specifically emphasized the need for national uniformity when it enacted this statute (*see* pages 3-4, *supra*); but the decision below imposes conflicting standards governing whether particular types of meat are "adulterated" — and therefore subjects meat processors to inconsistent obligations — depending upon where their product ends up being sold or served. This Court should grant review

to preserve the federally-regulated national market that Congress intended to create when it enacted the FMIA.

To begin with, the decision of the Wisconsin Court of Appeals squarely conflicts with *Boulahanis* v. *Prevo's Family Market, Inc.*, *supra*. In *Boulahanis*, the Michigan Court of Appeals held that the FMIA preempted claims arising out of pre-1994 sales of ground beef containing *E. coli*. 583 N.W.2d at 511-12. The court concluded that the Secretary's judgment at that time (that *E. coli* was not an adulterant in ground beef) constituted an "intentional decision not to regulate the presence of E. Coli * * * [that] carries the force of a positive enactment." *Id.* at 512. Accordingly, the court reasoned that the plaintiffs' common-law tort actions were preempted by federal law because "[h]olding defendants liable for failing to detect the presence of E. Coli bacteria in the meat purchased by plaintiffs in 1993 would run contrary to the USDA's then-existing determination that inspection for E. Coli bacteria was not required." *Ibid.*

Boulahanis is consistent, moreover, with the Michigan Court of Appeals' prior ruling in *Kircos* v. *Holiday Food Center, Inc.*, 477 N.W.2d 130 (Mich. Ct. App. 1991), which held that the FMIA preempts common-law tort claims by consumers who contract trichinosis after eating federally-inspected pork. *Id.* at 132-33 (state-law claims preempted because Secretary has not identified trichinae as an adulterant in fresh pork).

The trial court explicitly relied on *Boulahanis* in dismissing this action. App., *infra*, 49a. The Wisconsin Court of Appeals attempted to distinguish *Boulahanis* on two grounds. First, it noted this Court's explanation in *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002), that agency inaction might evidence *either* a federal mandate to leave the area unregulated *or* "'an intent to preserve state regulatory authority pending the adoption of

specific federal standards.'" App., *infra*, 34a-35a (quoting *Sprietsma*, 537 U.S. at 65). But that discussion in *Sprietsma* concerns a claim of *implied* preemption. 537 U.S. at 65-66. The instant case, by contrast, falls squarely within the FMIA's *express* preemption clause. Congress clearly expressed its intent to vest the Secretary with exclusive regulatory authority in this area, limiting the States' "concurrent jurisdiction" to "adulterated" meat; if the Secretary declares a type of meat to be unadulterated and fit for human consumption, the States are not free to impose a contrary requirement. There is no reason whatever to believe that *Sprietsma* would alter the Michigan court's view of express preemption under the FMIA.

Second, the Wisconsin court pointed to the fact that, "contrary to the situation in *Boulahanis*, the [FSIS] is now not only concerned with E. coli O157:H7, but, indeed, is striving to reduce its presence in meat * * *." App., *infra*, 35a. The Secretary's active regulation in this area — and her explicit distinction between intact meat and ground meat (*see* 67 Fed. Reg. at 62,326) — only underscores that conflicting or additional state requirements, such as common-law tort liability for shipping types of meat that the Secretary has deemed to be unadulterated, would interfere with Congress's plan to protect producers, consumers, and national markets through a uniform system of federal regulation grounded on the Secretary's expertise.

The declaration by the court below that *Boulahanis* is "irrelevant" is unsupported by any valid legal or factual distinction, and rests on nothing more than the Wisconsin Court of Appeals' disagreement with the Michigan Court of Appeals. That is a disagreement that should be resolved by this Court.

The decision of the Wisconsin Court of Appeals also conflicts with decisions of the Second, Eighth, and D.C. Circuits holding that the Secretary has broad rulemaking

authority under the FMIA and that courts cannot, therefore, dismiss her views out of hand. *See Grocery Mfrs. of Am., Inc.* v. *Gerace*, 755 F.2d 993, 1001-02 (2d Cir. 1985); *National Pork Producers Council* v. *Bergland*, 631 F.2d 1353, 1361-62 (8th Cir. 1980); *Public Citizen* v. *Foreman*, 631 F.2d 969, 975 (D.C. Cir. 1980).

In *Gerace*, the Second Circuit upheld a USDA interpretation of the statutory term "imitation" for purposes of the FMIA's labeling requirements. Although noting that it was "not bound by interpretive rules," the court concluded that "USDA's longstanding interpretation of the FMIA * * * branding provisions" was "a reasonable interpretation and therefore entitled to judicial respect." 755 F.2d at 1001-02 (citation omitted). In *Foreman*, the D.C. Circuit upheld the validity of a USDA regulation concerning the use of nitrites in cured meats despite a consumer group's allegation that those preservatives are "unsafe," explaining that "courts appropriately accord substantial deference to agencies' interpretations of the regulations they must administer, and that such deference is especially prudent in areas involving scientific and medical controversies." 631 F.2d at 975 (citations omitted). And, more generally, the Eighth Circuit recognized in *Bergland* that "the statutory grant of authority to the Secretary is broad, and no restrictions on the permissible types of standards are contained in the [FMIA]." 631 F.2d at 1362. Thus, as long as the Secretary's regulations "bear[] a rational relationship" to her congressionally-mandated duty to ensure that meat products are "'wholesome, not adulterated, and properly marked, labeled, and packaged,'" the court concluded that they are legitimate exercises of agency authority. *Id.* at 1361.

Whether or when meat bearing *E. coli* is "injurious to health" (21 U.S.C. § 601(m)(1)) is surely the sort of "scientific and medical controvers[y]" that cries out for expert agency

judgment. *Foreman*, 631 F.2d at 975; *cf. Community Nutrition*, 749 F.2d at 54 (need for "expert and technical judgment" in applying nonspecific statutory standards "suggests that this is an area in which courts must give great deference to the Secretary's judgments"). The Wisconsin Court of Appeals' determination that Congress barred it from even considering the Secretary's views on the meaning of "adulterated" is thus entirely at odds with the decisions in *Bergland*, *Foreman*, and *Gerace*.

* * *

In sum, the decision of the Wisconsin Court of Appeals undermines the central purposes of the FMIA, calls into question the broader regulatory powers of the Secretary of Agriculture, and conflicts with the decisions of other state and federal appellate courts. This Court should grant *certiorari*, reverse the judgment below, and thereby prevent the Wisconsin court from usurping federal rulemaking authority and disrupting a critically important federal regulatory program.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

RALPH A. WEBER
AMELIA L. MCCARTHY
SHAWN K. STEVENS
Reinhart Boerner Van Deuren S.C.
1000 North Water Street
P.O. Box 2965
Milwaukee, WI 53201
(414) 298-1000

ANDREW J. PINCUS
Counsel of Record
RICHARD B. KATSKEE
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

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COURT OF APPEALS DECISION
DATED AND FILED
May 13, 2003

Appeal No. 02-1939
STATE OF WISCONSIN

ESTATE OF BRIANNA L. KRIEFALL, DECEASED, BY HER SPECIAL ADMINISTRATOR, DOUGLAS A. KRIEFALL, DOUGLAS A. KRIEFALL, CONNIE J. KRIEFALL, AND CHAD KRIEFALL, A MINOR, BY HIS GUARDIAN AD LITEM, WILLIAM M. CANNON, PLAINTIFFS-APPELLANTS,

HUMANA EMPLOYERS HEALTH INSURANCE CO., A WISCONSIN INSURANCE CORPORATION, INVOLUNTARY-PLAINTIFF,

v.

SIZZLER USA FRANCHISE, INC., A FOREIGN CORPORATION, DEFENDANT-THIRD-PARTY PLAINTIFF-CO-APPELLANT,

FEDERAL INSURANCE CO., A FOREIGN INSURANCE CORPORATION, E & B MANAGEMENT CO. WAUKESHA, INC., A WISCONSIN CORPORATION, SECURA INSURANCE, A WISCONSIN INSURANCE CORPORATION, SYSCO SERVICES OF EASTERN WISCONSIN, A WHOLLY OWNED SUBSIDIARY OF SYSCO CORPORATION, A FOREIGN CORPORATION, FIDELITY AND GUARANTY INSURANCE CO., A FOREIGN INSURANCE CORPORATION, LEE M. ESCHENBACH, STEVEN C. BOYSA, AAA INSURANCE CO., AND BBB INSURANCE CO., DEFENDANTS,

EXCEL CORPORATION, A FOREIGN CORPORATION, AND AMERICAN HOME ASSURANCE CO., A FOREIGN INSURANCE CORPORATION, DEFENDANTS-RESPONDENTS,

v.

LEE M. ESCHENBACH, STEVEN C. BOYSA, AAA INSURANCE CO., BBB INSURANCE CO., CARGILL, INC., A FOREIGN CORPORATION, AND EXCEL FOOD DISTRIBUTION, INC., A FOREIGN CORPORATION, THIRD-PARTY DEFENDANTS.

ERVIN J. LESAK AND FLORENCE LESAK, PLAINTIFFS-CO-APPELLANTS,

v.

E & B MANAGEMENT CO. WAUKESHA, INC., DEFENDANT, EXCEL CORPORATION, DEFENDANT-RESPONDENT.

JEFFREY FORTIER, JUDITH FORTIER, TRISTAN FORTIER, AND CARLY FORTIER, PLAINTIFFS-CO-APPELLANTS,

GREAT WEST LIFE & ANNUITY INSURANCE, INVOLUNTARY-PLAINTIFF,

v.

EXCEL CORPORATION, DEFENDANT-RESPONDENT.

KEVIN MCCORMICK, SANDY MCCORMICK, AND KELSEA MCCORMICK, PLAINTIFFS-CO-APPELLANTS,

BLUE CROSS BLUE SHIELD UNITED,
INVOLUNTARY-PLAINTIFF,

v.

EXCEL CORPORATION, DEFENDANT-RESPONDENT.

APPEAL from judgments of the circuit court for Milwaukee County: MICHAEL P. SULLIVAN, Judge. *Reversed.*

Before FINE, SCHUDSON and HOOVER, JJ.

¶ 1 FINE, J.

This is a consolidated appeal from the trial court's grant of summary judgment to Excel Corporation, a meat processor, dismissing claims against Excel for damages allegedly caused by Excel's sale to a Milwaukee area Sizzler restaurant of beef contaminated with the bacterium E. coli O157:H7. The plaintiffs involved in this appeal contend that E. coli bacteria from the meat sold by Excel to the Sizzler restaurant contaminated other food that was eaten by either them or those through whom they derive their claims.[1] Sizzler USA

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[1] The plaintiffs involved in this appeal are: The Estate of Brianna L. Kriefall, Douglas A. Kriefall, Connie J. Kriefall, and Chad Kriefall in Milwaukee County Circuit Court Case No. 00-CV-006463; Ervin J. Lesak and Florence Lesak in Milwaukee County Circuit Court Case No. 00-CV-006360; Jeffrey Fortier, Judith Fortier, Tristan Fortier, and Carly Fortier in Milwaukee County Circuit Court Case No. 00-CV-008756; and Kevin McCormick, Sandy McCormick, and Kelsea McCormick in Milwaukee County Circuit Court Case No. 00-CV-008793. Only the Kriefalls, the Lesaks, and Sizzler USA have filed appellate briefs. A joint *amici curiam* brief has been filed by The American Meat Institute, the National Chicken Council, the National Meat Association, the National Turkey Federation, the

Franchise, Inc., the franchisor of the Milwaukee Sizzler restaurant, is a defendant in some of the actions and also appeals from the trial court's grant of summary judgment dismissing Sizzler USA's claims against Excel. The trial court ruled that the claims against Excel were barred by the federal-preemption doctrine. We disagree and reverse.

I.

¶ 2 In July of 2000, a number of persons were injured and three-year-old Brianna Kriefall died from eating food that everyone party to this appeal, the plaintiffs, Sizzler USA, and Excel, recognize was cross-contaminated by E. coli O157:H7 bacteria from meat sold by Excel. Although some of the parties' arguments on appeal focus on both to what extent the E. coli contamination of the Excel beef was a cause of Brianna's death and the other injuries, and whether Excel was either negligent or sold a dangerously defective product, the only issue we need decide on this appeal is whether the claims against Excel are preempted by federal law. We conclude that federal preemption does not close the doors of Wisconsin's courts to the claims against Excel; the merits of those claims still have to be determined.

¶ 3 Federal preemption is based on Article VI of the United States Constitution, which makes federal law "the supreme Law of the Land." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). As material here, there are two steps to an analysis of whether federal regulation preempts state common-law claims: (1) whether the controlling federal statute "expressly pre-empts common-law claims," and, if not, (2) whether "the potential conflict between diverse state rules and the federal interest in a uniform system of regulation impliedly pre-empts such claims." *Sprietsma v.*

North American Meat Processors Association, and the Southwest Meat Association. All submissions to this court provided helpful analyses.

Mercury Marine, 537 U.S. 51, 123 S.Ct. 518, 522-523, 154 L.Ed.2d 466 (2002); *see also Geier v. American Honda Motor Co.,* 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000) ("ordinary" preemption principles may bar state claims even though those claims are not expressly preempted by the applicable federal statute).[2]

¶ 4 The interstate sale of beef and other meat products intended for human consumption is regulated by the Federal Meat Inspection Act, 21 U.S.C. §§ 601-695. The Act has a preemption clause, which provides, as applicable here:

> Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter [§§ 601-624], which are in addition to, or different than those made under this chapter may not be imposed by any State . . . This chapter shall not preclude any State . . . from making requirement [*sic*] or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

21 U.S.C. § 678.[3] This section thus: (1) prevents states from

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[2] *Sprietsma* also identified a third element, which does not apply here: whether a decision by the agency vested by Congress with regulatory responsibility to not prescribe a safety standard preempts claims seeking to impose liability on a manufacturer in a regulated industry for the manufacturer's failure to adopt that safety standard. 123 S.Ct. at 522-523.

[3] 21 U.S.C. § 678 reads in full:

> Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may

impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement [*sic*] or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

We assume, without deciding, that the word "requirements" encompasses state common-law claims, although the law on this is not yet entirely settled. Thus, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), the preemption clause provided that, as material here:

"[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement —

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Id., 518 U.S. at 481-482, 116 S.Ct. 2240. Justice John Paul Stevens, writing only for himself and Justices Anthony M. Kennedy, David H. Souter, and Ruth Bader Ginsburg (and not "the" Court, as some of the appellants represent), rejected the view "that any common-law

cause of action is a 'requirement' which alters incentives and imposes duties 'different from, or in addition to,' the generic federal standards that the [Food and Drug Administration] has promulgated in response to mandates under the [Medical Device Amendments of 1976]." *Id..*, 518 U.S. at 486-487, 116 S.Ct. 2240. The same plurality, however, specifically declined to hold "that common-law duties are never 'requirements' within the meaning of the [Medical Device act's preemption clause] and that the statute therefore never pre-empts common-law actions." *Id.*, 518 U.S. at 502, 116 S.Ct. 2240. Four years earlier, however, Justice Stevens, this time writing for himself, Chief Justice William H. Rehnquist, and Justices Byron R. White and Sandra Day O'Connor, opined in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), that a preemption phrase in that case, which sought damages for the cigarette-related death of the plaintiff's decedent, encompassed state-court claims. *Id.*, 505 U.S. at 520-523, 112 S.Ct. 2608. The phrase provided: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.*, 505 U.S. at 515, 112 S.Ct. 2608. Justice Stevens wrote:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."
>
> . . . .
>
> Moreover, common-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose "requirements or prohibitions."

Id., 505 U.S. at 521, 112 S.Ct. 2608 (quoted source omitted; bracketing by Justice Stevens). *See also Lynnbrook Farms v.*

imposing "[r]equirements . . . with respect to premises, facilities and operations of any establishment at which inspection is provided under" 21 U.S.C. §§ 601-624 that "are in addition to, or different than those made under" the Act, and (2) permits states to impose "requirement[s]" and to take "other action" that is "consistent" with the Act "with respect to any other matters regulated under" the Act.

¶ 5 For the purpose of this appeal, we assume that all the facts asserted by Excel are true. *See City of Milwaukee v. Burnette,* 2001 WI App 258, ¶ 8, 248 Wis.2d 820, 834, 637 N.W.2d 447, 454 (court reviewing grant or denial of summary judgment ignores disputed facts unless those facts are material to the legal issue to be decided). We analyze whether either 21 U.S.C. § 678 expressly preempts the tort claims asserted here or whether those claims are impliedly preempted by federal law because they present "an actual conflict with a federal objective." *Geier,* 529 U.S. at 871, 120 S.Ct. 1913. Whether state tort claims are preempted by federal law is a legal issue that we review *de novo. International Ass'n of Machinists & Aerospace Workers v. United States Can Co.,* 150 Wis.2d 479, 487, 441 N.W.2d 710, 713 (1989), *cert. denied,* 493 U.S. 1019, 110 S.Ct. 718, 107 L.Ed.2d 738.

Smithkline Beecham Corp., 79 F.3d 620, 627 (7th Cir.1996) ("State tort actions can therefore be as much of a threat to national uniformity as affirmative state regulation.") (relying on Justice Stevens's plurality opinion in *Cipollone,* but mistakenly referring to it as the view of "[t]he Supreme Court"). We also assume, without deciding, that the claims asserted here against Excel would, if successful, affect Excel's "operations" by encouraging or even compelling Excel to change those "operations" in order to avoid future liability caused by E. coli contaminated meat.

II.

¶ 6 Congressional intent concerning the interstate sale of meat is set out in 21 U.S.C. § 602, which we reprint in full:

> Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate

> such commerce, and to protect the health and welfare of consumers.[4]

(Footnote added.) Thus, as expressed in § 602, Congress wanted to: (1) protect consumers "by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged"; (2) protect those in the meat-production chain from unscrupulous competitors; and (3) "prevent and eliminate burdens upon [interstate or foreign] commerce." *Ibid.* The overriding congressional purpose is, however, public safety — as evidenced by not only the section's direct statements to that effect but also by one of the stated rationales underlying the concurrent congressional desire to preserve fair competition for those who sell wholesome and properly packaged and labeled meat. Accordingly, congressional focus is on ensuring that only meat that is "not adulterated" makes it into the interstate-commerce market. *Ibid.*

¶ 7 The Excel beef that was shipped to the Sizzler restaurant, and according to the plaintiffs caused their illnesses

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[4] "Meat food product" is defined by the Meat Inspection Act as:

> [A]ny product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

21 U.S.C. § 601(j).

and Brianna's death, were wrapped "intact" (not ground or chopped or minced or shredded) cuts of sirloin muscle when they left the Excel plant. Excel's preemption argument is based on two main contentions. First, it asserts that the sale of intact meat contaminated with E. coli O157:H7 is not "adulterated" under federal law. Accordingly, under its view, permitting the claims to proceed would prohibit or punish that which federal law allows, thereby running afoul of the preemption clause. Second, it argues that the meat left its plant after it was inspected and approved by government inspectors, and thus, again, permitting these claims against it would, in effect, prohibit or punish that which federal law allows. An evaluation of these contentions requires an analysis of the Meat Inspection Act and the applicable governing regulations.

¶ 8 Most if not all congressional enactments delegate their implementation to one or more administrative agencies. Some statutes have an all-encompassing clause and state "simply that the agency may 'make ... such rules and regulations as may be necessary to carry out the provisions of this Act.'" *See Mourning v. Family Publ'ns Serv., Inc.,* 411 U.S. 356, 369, 93 S.Ct. 1652, 36 L.Ed.2d 318 (1973) (quoting, as an example, § 8 of the United States Housing Act of 1937, as amended, 42 U.S.C. § 1408). When that is the situation, the administrative agency's regulations are followed as long as they are "'reasonably related to the purposes of the enabling legislation.'" *Ibid.* (quoted source omitted). Other delegations of regulatory authority are more limited, and the agency is authorized to promulgate regulations only within narrow confines. In such a situation, the statute, not a regulation that may conflict with the statute, governs, *Touche Ross & Co. v. Redington,* 442 U.S. 560, 577 n.18, 99 S.Ct. 2479, 61 L.Ed.2d 82 (1979) ("[T]he language of the statute and not the rules must control."); *Koshland v. Helvering,* 298 U.S. 441, 447, 56 S.Ct. 767, 80 L.Ed. 1268 (1936) (where "provisions of the act are unambiguous, and its directions specific, there is no power to amend it by regulation"), because "[i]t is axiomatic that an

administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress," *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988).

¶ 9 Congress delegated enforcement of the Meat Inspection Act to the Secretary of the United States Department of Agriculture or designee. 21 U.S.C. §§ 602, 601(a). The Secretary has, in turn, delegated authority under the Meat Inspection Act, with exceptions that are not material here, to the Under Secretary for Food Safety, AGRICULTURE, 7 C.F.R. § 2.18(a)(1)(ii)(B), who, in turn, subdelegated that authority to the Administrator of the Food Safety and Inspection Service, AGRICULTURE, 7 C.F.R. § 2.53(a)(2)(ii).

¶ 10 In contrast to some other delegations of authority by Congress to administrative agencies, Congress's delegation here is focused. Thus, as we will see, although the Secretary has a wide berth in implementing the congressional mandate to inspect meat-processing plants, the Secretary has only limited authority to affect the congressional definition of "adulterated," other than in the area of labeling (21 U.S.C. § 601(m)(5), (7)-(9)). And that limitation, as we will explain, is critical in this case because of Excel's argument that the Secretary views intact meat contaminated with E. coli O157:H7 as not "adulterated."

III.

¶ 11 Whether the claims against Excel are expressly preempted by 21 U.S.C. § 678 because they would impose requirements "with respect to premises, facilities and operations . . . which are in addition to, or different than those made under" the Meat Inspection Act turns on: (1) what is "adulterated" under the Act, and (2) the nature of federal inspection of meat-processing plants under the Act.

A. *The Act's Definition of "Adulterated."*

¶ 12 The word "adulterated" has a special meaning under the Meat Inspection Act, and, significantly, the Secretary is given authority to affect the statute's definition in only one limited instance:

> The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance . . . which may, in the judgment of the Secretary, make such article unfit for human food;
>
> . . . .
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; [or]
>
> (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

21 U.S.C. § 601(m). We look at these subsections in turn.

¶ 13 *Subsection (1).* The E. coli strain that killed Brianna and made the others sick is a "deleterious substance which *may*

render [meat] injurious to health." There is no dispute about this. Thus, under the first part of 21 U.S.C. § 601(m)(1), meat that either "bears or contains" E. coli O157:H7 (the "deleterious substance") is "adulterated." That E. coli O157:H7 contamination can be rendered non-"injurious to health" by cooking thoroughly, as discussed below, does not negate this; Congress used the phrase "may render," not "in every circumstance renders." Moreover, if the E. coli bacteria is not considered to be "an added substance," because it comes from some of the animals themselves and is not either applied or supplied during the slaughtering process (although we do not decide this), it cannot be said that the E. coli strain "does not ordinarily render [the meat on or in which it appears] injurious to health." Accordingly, meat contaminated by E. coli O157:H7 is also "adulterated" under the second part of § 601(m)(1).

¶ 14 *Subsection (2)(A).* This section defers to the Secretary (and thus, derivatively, to the Food Safety and Inspection Service) to determine whether the contaminating substance that is alleged to make the affected meat "adulterated" does, in fact, "make such article unfit for human food." As we will see, the Food Safety and Inspection Service determined that E. coli-infected meat is not unfit as human food as long as it is: (1) an intact cut, and (2) treated by cooking or otherwise to kill the surface E. coli contamination.

¶ 15 *Subsection (3).* Meat contaminated by the E. coli strain that was on the Sizzler meat falls within this definition of "adulterated" because the E. coli made the infected meat at least "in part . . . unsound, unhealthful, unwholesome, or otherwise unfit for human food" within the meaning of the all-encompassing phrase "for any other reason."

¶ 16 *Subsection (4).* Meat contaminated by E. coli O157:H7 also falls within this definition of "adulterated" because it is "prepared" in such a way "whereby it may have been rendered injurious to health."

¶ 17 The only regulations defining "adulterated" in the context here are found in ANIMALS AND ANIMAL PRODUCTS, 9 C.F.R. § 301.2:

> *Adulterated.* This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> . . . .
>
> (3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; [or]
>
> (4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Excel contends that the meat it produced that ultimately went to the Sizzler restaurant was not "adulterated" because the Food Safety and Inspection Service has determined that E. coli adulterates only non-intact meat — that is, meat that is ground or otherwise processed so that the E. coli contamination is not restricted to meat surfaces that are seared, broiled, or otherwise heated to kill the bacteria. To put Excel's argument in context, we examine in detail the Food Safety and Inspection Service's determinations.

¶ 18 In a policy statement published in the Federal Register on January 19, 1999, the Food Safety and Inspection Service opined that it:

> believes that in evaluating beef products contaminated with *E. coli* O157:H7, intact cuts of muscle that are to be distributed for consumption as intact cuts should be distinguished from non-intact products, as well as from intact cuts of muscle that are to be further processed into non-intact product prior to distribution for consumption.

BEEF PRODUCTS CONTAMINATED WITH ESCHERICHIA COLI O157:H7, 64 FED.REG. 2803, 2804 (Jan. 19, 1999). The Inspection Service further explained:

> Non-intact beef products include beef that has been injected with solutions, mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees (*e.g.,* beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros). Pathogens may be introduced below the surface of these products as a result of the processes by which they are made. In addition, non-intact beef products include those beef products in which pathogens may be introduced below the surface by a comminution process such as chopping, grinding, flaking, or mincing (*e.g.,* fresh veal sausage and fabricated beef steak).
>
> Intact cuts of beef that are to be further processed into non-intact cuts prior to distribution for consumption must be treated in the same manner as non-intact cuts of beef, since pathogens may be introduced below the surface of these products when they are further processed into non-intact products. Manufacturing trimmings (*i.e.,* pieces of meat

> remaining after steaks, roasts, and other intact cuts are removed) are an example of this type of product. Although manufacturing trimmings may be intact, they are generally further processed into non-intact products.
>
> The Agency believes that with the exception of beef products that are intact cuts of muscle that are to be distributed for consumption as intact cuts, an *E. coli* O157:H7-contaminated beef product must not be distributed until it has been processed into a ready-to-eat product — *i.e.*, a food product that may be consumed safely without any further cooking or other preparation. Otherwise, such products (*i.e.*, non-intact products and intact cuts of muscle that are to be further processed into non-intact products prior to distribution for consumption) must be deemed adulterated. Intact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed. Consequently, such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated.

Ibid. (footnote omitted). The meat sold by Excel arrived at the Sizzler restaurant as wrapped intact cuts of beef that bore labels warning the Sizzler employees to cook the meat thoroughly, to keep the raw meat away from other foods, and to wash working surfaces, tools, utensils, and hands after their contact with raw meat. Excel contends that this, together with the fact that the meat left its plant approved by the federal inspection process, lets it off the hook. There are two problems with this contention.

¶ 19 First, when Excel shipped the meat that was sold to the Sizzler restaurant, meat processors like Excel were required by regulations governing the processors' assessment of food-safety

hazards in their plants to consider "the intended use or consumers of the finished product." ANIMALS AND ANIMAL PRODUCTS, 9 C.F.R. § 417.2(a)(2). This regulation was effective on January 26, 1998, for establishments employing more than 500 persons. PATHOGEN REDUCTION; HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS, 61 FED.REG. 38806, 38869 (July 25, 1996). According to evidence in the record, significantly more than 500 persons worked at the Excel plant when it produced the meat that was sold to the Sizzler restaurant. The scope of this direction to consider the consumers' "intended use" was underscored by the Food Safety and Inspection Service in a policy statement published in the Federal Register on October 7, 2002:

> Even establishments that produce intact product will need to reassess their [hazard-analysis] plans based on the new *E. coli* O157:H7 data [indicating that the bacterium "is more prevalent than was previously thought" "and that this pathogen may he a hazard that is reasonably likely to occur at all stages of handling raw beef products"]. These establishments are required to reassess their [hazard-analysis] plans because much intact beef product may be used to make non-intact product such as ground beef. According to [9 C.F.R.] § 417.2(a)(2), establishments are required to identify the intended use or consumers of the finished product. Therefore, to be able to determine the adequacy of their [hazard-analysis] plans, establishments that produce intact beef products need to determine whether their products will be used to produce raw, non-intact product.

E. COLI O157:H7 CONTAMINATION OF BEEF PRODUCTS, 67 FED.REG. 62325, 62329 (Oct. 7, 2002). Thus, Excel's hazard-analysis plan recognized that its intact cuts of beef were "intended to be sold raw . . . for further processing at retail."

¶ 20 Second, although Congress has in 21 U.S.C. § 601(m)(2)(A) delegated to the Secretary the responsibility to make a "judgment" whether "any . . . added deleterious substance" makes the meat to which the substance is added "unfit for human food," Congress has itself, in 21 U.S.C. § 601(m)(1), (3), & (4), defined "adulterated" without seeking the Secretary's input. As discussed earlier, insofar as the statutory definitions of "adulterated" conflict with the gloss put on them by the Food Safety and Inspection Service, the statutory definition controls. *Touche Ross,* 442 U.S. at 577 n. 18, 99 S.Ct. 2479 ("[T]he language of the statute and not the rules must control."). The focus of subsections (1), (3), and (4) of § 601(m) is on people's health and safety. None of the definitions of "adulterated" in the Act makes a distinction between intact or non-intact meat, and the Food Safety and Inspection Service was powerless to add that distinction to Congress's definitions of "adulterated" in subsections (1), (3), and (4). *See Koshland,* 298 U.S. at 447, 56 S.Ct. 767 (agency has no power to contravene a statute where its "provisions . . . are unambiguous, and its directions specific"). Moreover, as noted, even the Department's own regulations defining the word "adulterated," as opposed to its less-formal pronouncements, make no distinction between contaminated intact meat and contaminated non-intact meat.

¶ 21 Based on the foregoing, we reject Excel's contention that the claims against it are barred because holding it liable for shipping in interstate commerce intact meat contaminated with E. coli O157:H7 would contravene the Act's express "premises, facilities and operations" preemption clause. We now turn to whether the Act's meat-inspection provisions and the regulations promulgated thereunder expressly preempt those claims.

B. *Federal Inspection Under the Act.*

¶ 22 As we have seen, the Meat Inspection Act's preemption clause prohibits states from imposing requirements

"with respect to premises, facilities and operations of any establishment," which, like Excel, are regulated by the Act, that "are in addition to, or different than those made under" the Act. 21 U.S.C. § 678. Again, we assume, without deciding, that the claims asserted here against Excel would, if successful, affect Excel's "operations."

¶ 23 As material to this appeal, 21 U.S.C. § 603(a) governs the inspection of meat and meat food products:

> For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle ... before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce ... all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.[5]

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[5] 21 U.S.C. § 603(a) provides in full:

> For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all cattle, sheep, swine, goats, horses, mules, and other equines found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to

(Footnote added.) Effective January 26, 1998, for meat processors with more than 500 employees, the Food Safety and Inspection Service delegated to the meat processors themselves the responsibility of coming up with procedures, designated as a Hazard Analysis and Critical Control Point system, adapted to the processors' own circumstances, to safeguard the wholesomeness of the meat they produce:

> Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

9 C.F.R. § 417.2(a)(1); PATHOGEN REDUCTION, 61 FED.REG. at 38869. As further summarized by the Department in a June 2000 report issued by its Office of Inspector General, the new program was designed to "reverse[ ]" the arrangement under which "the production of meat and poultry products was monitored at every stage by Government employees" to a system that "allow[ed] a plant to monitor itself." U.S.D.A. REP. NO. 24001-3-At, at 1 (2000). Thus, the new plan, as phrased by the report, "gave industry, not Government, the primary responsibility for ensuring the safety of meat and poultry products." *Ibid.*

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a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

¶ 24 In a report dated July 25, 1996, the Food Safety and Inspection Service detailed the nature of the extensive inspection overhaul:

> The Food Safety and Inspection Service is establishing requirements applicable to meat and poultry establishments designed to reduce the occurrence and numbers of pathogenic micro-organisms on meat and poultry products, reduce the incidence of foodborne illness associated with the consumption of those products and provide a new framework for modernization of the current system of meat and poultry inspection. The new regulations (1) require that each establishment develop and implement written sanitation standard operating procedures; (2) require regular microbial testing by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for Salmonella that slaughter establishments and establishments producing raw ground products must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as [Hazard Analysis and Critical Control Point systems].

PATHOGEN REDUCTION, 61 FED.REG. at 38806 (acronyms omitted). E. coli O157:H7 is a bacterium associated with "fecal contamination." *Id.* at 38837. The report noted that the overhaul was triggered by "[r]ecent outbreaks of foodborne illness and studies conducted over the past decade ... [that] have established the need for fundamental change in the [Food Safety and Inspection Service] meat and poultry inspection program to improve food safety, reduce the risk of foodborne illness in the United States, and make better use of the Agency's resources." *Id.* at 38807 (acronyms omitted).

¶ 25 The Service also explained that the Hazard Analysis and Critical Control Point systems "focus on attributes affecting product safety, not those affecting economic adulteration or quality" and that it was "a conceptually simple system whereby meat and poultry establishments can identify and evaluate the food safety hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keeping them within acceptable limits, monitor the performance of controls, and maintain records routinely." *Id.* at 38814. Among the matters that meat processors had to consider in establishing an applicable Hazard Analysis and Critical Control Point plan for their facilities were:

> (1) What potential hazards may be present in the animals to be slaughtered or the raw materials to be processed? (2) What are the avenues that might lead to contamination of finished product with pathogenic microorganisms, hazardous chemicals, or other potentially hazardous contaminants? (3) What is the likelihood of such contamination and what are the means for preventing it? (4) Does the food contain any ingredient historically associated with a known microbiological hazard? (5) Does the food permit survival or multiplication of pathogens or toxin formation during processing? (6) Does the process include a controllable processing step that destroys pathogens? (7) Is it likely that the food will contain pathogens and are they likely to increase during the times and conditions under which the food is normally stored before being consumed? (8) What product safety devices are used to enhance consumer safety (e.g., metal detectors, filters, thermocouples)? (9) Does the method of packaging affect the multiplication of pathogenic microorganisms and/or the formation of toxins? (10) Is the product epidemiologically linked to a foodborne disease?

Id. at 38815. The Service also focused specifically on E. coli contamination:

> In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material and ingesta, both within the gastrointestinal tract and on the exterior surfaces of animals going to slaughter. Therefore, without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Additionally, once introduced into the establishment environment, the organisms may be spread from carcass to carcass.
>
> Because the microbial pathogens associated with fecal contamination are the single most likely source of potential food safety hazard in slaughter establishments, preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments. Further, because such contamination is largely preventable, controls to address it will be a critical part of any slaughter establishment's [Hazard Analysis and Critical Control Point] plan. Most slaughter establishments already have in place procedures designed to prevent and remove visible fecal contamination.
>
> There is general agreement within the scientific community that generic E. coli is the best single microbial indicator for fecal contamination. [The Food Safety and Inspection Service], therefore, is requiring that establishments slaughtering livestock or poultry begin testing for E. coli.

Id. at 38837. The upshot of all this is that Excel and the rest of the meat-processing industry were well aware of both the

danger to health posed by E. coli contamination and the need for their Hazard Analysis and Critical Control Point plans to address eliminating that contamination in their respective facilities. Indeed, the dangers were deemed to be so significant that the Food Safety and Inspection Service saw as the goal of a facility's Hazard Analysis and Critical Control Point System the *prevention* of fecal contamination:

> Establishments that slaughter livestock and poultry currently have an obligation to control the slaughter and sanitary dressing process so that contamination with fecal material and other intestinal contents is prevented. This means that establishments must maintain sanitary conditions and use good manufacturing practices to avoid contamination with visible feces and ingesta and associated bacteria.

Id. at 38838. The Service recognized, however, that mere visible inspection was insufficient:

> [Food Safety and Inspection Service] inspectors apply a zero tolerance performance standard for visible feces and ingesta on dressed carcasses. As a practical matter, however, *additional measures must be taken if inspectors are to assess the extent to which the invisible bacteria associated with feces and ingesta may be present on the carcass.*
>
> [The Food Safety and Inspection Service] has concluded, based on its proposal and the comments received, that the current practice of organoleptic examination by inspectors and the physical removal of visible contamination by establishments needs to be supplemented with an establishment-conducted microbial verification activity. This microbial testing is designed to verify, for the establishment and [the Food Safety and Inspection Service], that the establishment has controlled its slaughter process

> with respect to *prevention and removal* of fecal material and ingesta *and* associated bacteria.

Ibid. (emphasis added).[6] The Food Safety and Inspection Service characterized the goal as requiring "a slaughter establishment's adherence to zero tolerance for fecal contamination." *Id.* at 38850. Indeed, in a report published in the Federal Register on October 7, 2002, the Service repeated that it "considers an acceptable reduction for *E. coli* O157:H7 to be a reduction to an undetectable level." E. coli O157:H7, 67 FED.REG. at 62329.

¶ 26 Significantly, in light of Excel's focus on the distinction between intact cuts of beef, which were sold to the Milwaukee Sizzler, and non-intact beef, the Service's statement that E. coli contamination must be reduced to "an undetectable level" appears on the same page of the Federal Register reiterating the already in-place requirement in 9 C.F.R. § 417.2(a)(2) that meat processors identify and consider "the intended use or consumers of the finished product." E. COLI O157:H7, 67 FED.REG. at 62329. Even in 1996, however, the Food Safety and Inspection Service recognized that "foodborne illness" was "a substantial and intolerable public health problem" and explained why it was so important for processors to consider what would happen to even intact meat after it left the processors' plants:

> [T]he health effects of enteric pathogens are relatively well documented. If the pathogens enter the food supply, they do, under certain conditions, cause foodborne illness. If their presence can be prevented, no amount of temperature abuse, mishandling or undercooking can lead to foodborne illness.

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[6] "Organoleptic" is defined as "affecting or making an impression upon one or more of the organs of special sense." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1590 (1993).

PATHOGEN REDUCTION, 61 FED.REG. at 38962. Given the realities of what it saw as consumers' food-handling patterns, the Food Safety and Inspection Service bored in on the only effective way to reduce or eliminate food-borne illness:

> Occurrence of foodborne disease is a multi-step process. The first, and critical, step is the introduction of a pathogen into or onto the raw product. If a pathogen is present, then subsequent temperature abuse or mishandling may permit bacterial counts to increase to levels which increase the likelihood that illness will occur; mishandling may result in cross- contamination of other foods which are not cooked before being eaten; or improper cooking may not kill all pathogenic bacteria present in the product. In these instances, it may be said that the illness was "caused" by improper handling. However, *disease would not have occurred if the pathogen had not been present on the raw product in the first place.*

Id. at 38966 (emphasis added). We now turn to how all this affects whether the claims against Excel are barred by the express-preemption clause.

IV.

¶ 27 We start our analysis, as we must, with the words of the statute. In discerning whether Congress intended the Meat Inspection Act to preempt state claims we must give to unambiguous statutory language the meaning it denotes. *Sprietsma,* 123 S.Ct. at 526, 123 S.Ct. 518 (statute's "'plain wording'" of preemption clause "'necessarily contains the best evidence of Congress' pre-emptive intent'") (quoted source omitted). This is also the general rule of statutory construction in Wisconsin. *Anderson v. City of Milwaukee,* 208 Wis.2d 18, 25, 559 N.W.2d 563, 566 (1997) (legislative intent discerned from statute's plain language); *Jungbluth v. Hometown, Inc.,*

201 Wis.2d 320, 327, 548 N.W.2d 519, 522 (1996) (plain statutory language is applied as it is written).

¶ 28 Although our analysis is governed by the statute's words, interpretation and application of preemption "language does not occur in a contextual vacuum," but must be "informed by two presumptions about the nature of pre-emption." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). First, the United States Supreme Court has "long presumed that Congress does not cavalierly pre-empt state-law causes of action," and thus the Court "'start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Ibid.* (quoted source omitted). Further, this presumption against preemption applies to not only "whether Congress intended any pre-emption at all," but also to the scope of any preemption that Congress may have intended. *Ibid.*

¶ 29 Second, the "'purpose of Congress is the ultimate touchstone' in every pre-emption case." *Ibid.* (quoted source omitted). As we have seen, Congressional intent "primarily is discerned from the language of the pre- emption statute and the 'statutory framework' surrounding it," and, also, "the 'structure and purpose of the statute as a whole' as revealed not only in the text but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Id.,* 518 U.S. at 485-486, 116 S.Ct. 2240 (quoted source and internal citations omitted).

A.

¶ 30 The express preemption clause here prohibits any state from imposing on producers regulated by the Meat Inspection Act any "[r]equirements within the scope of [the Act] with respect to premises, facilities and operations . . . which are in addition to, or different than those made under" the Act. 21 U.S.C. § 678. There is, however, a savings clause that, as we

have also seen, permits states to "make[ ] requirement[s] or tak[e] other action, consistent with [the Act], with respect to any other matters regulated under this [Act.]" *Ibid.*

¶ 31 On its surface, the phrase "with respect to premises, facilities and operations" applies only to the physical plant, the type and quantity of various categories of equipment, and the method of running the business. Thus, without deciding this, it seems to us that a state law that required a meat processor to employ a certain number of quality-control personnel or to irradiate its meat would fall within the express-preemption provision. But it is one thing to view the scope of the preemption clause to encompass meat inspection, meat treatment, or, indeed, the entire reach of the Hazard Analysis and Critical Control Point program, and entirely different to hold that state claims based on the sale of meat contaminated with E. coli O157:H7 are preempted by the clause. *Medtronic* makes this clear.

¶ 32 *Medtronic* concerned a suit for damages sustained by a person injured by an allegedly negligently manufactured and defective pacemaker part. *Id.*, 518 U.S. at 480-481, 116 S.Ct. 2240. The preemption clause there was similar to the one here, and provided, as material:

> "[N]o State ... may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."

Id., 518 U.S. at 481-482, 116 S.Ct. 2240. *Medtronic* held that the claims in that case were not preempted because the

"violations of common-law duties" for which the damages were sought were either "parallel" to the requirements set out in the federal statute, or more narrow than those requirements. *Id.*, 518 U.S. at 495, 116 S.Ct. 2240. *Medtronic* explained:

> Nothing in [the preemption clause] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that these violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Ibid. A similar analysis governs this case.

¶ 33 No one disputes but that the major goal of the Meat Inspection Act is to prevent the sale of "adulterated" meat products. As we have explained in Part III.A. of this opinion, the Excel meat that was sold to the Sizzler restaurant was "adulterated" as Congress defined that word, even though the meat left the Excel facility as intact cuts. Thus, a claim premised on damages resulting from the sale of "adulterated" meat, in the words of *Medtronic,* "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Ibid.*

¶ 34 By the same token, and as seen in Part III.B. of this opinion, a goal of the Food Safety and Inspection Service and the Hazard Analysis and Critical Control Point plans it implements is to "prevent" fecal and E. coli contamination--what the agency called "zero tolerance" for fecal contamination and the concomitant reduction of the E. coli bacterium to an "undetectable level." PATHOGEN REDUCTION, 61 FED.REG. at 38850; E. COLI O157:H7, 67 FED.REG. at 62329. Here also, in the words of *Medtronic,* claims based on allegations that Excel meat sold to the Sizzler restaurant had detectable levels of E. coli contamination "merely provide[ ] another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Medtronic,* 518 U.S. at 495, 116 S.Ct. 2240. Indeed, the Hazard Analysis and Critical Control Point program leaves it largely to the processors themselves to determine how best to achieve the goals of zero tolerance for bacteria-laden fecal matter and undetectable levels of E. coli O157:H7. Thus, a processor's responsibility to produce wholesome, non-pathogenic meat is, under the Act's inspection- mandate and the interpretation of the Food Safety and Inspection Service of that mandate, parallel to and not divergent from the processor's goal of avoiding tort-claims liability.

¶ 35 Furthermore, insofar as the preemption doctrine implicates a federal need for uniformity of regulation, *see Sprietsma,* 123 S.Ct. at 523, the federal inspection scheme here *eschews* uniformity in favor of non-uniform plant-by- plant Hazard Analysis and Critical Control Point plans developed by the plant operators themselves. Simply put, rather than a nation-wide uniform, one-size- fits-all approach present in so many preemption cases, the Food Safety and Inspection Service now lets meat processing plants monitor themselves with only comparatively minimal federal oversight. PATHOGEN REDUCTION, 61 FED.REG. at 38852 ("The Agency is responsible for establishing and enforcing reasonable standards; it intends to give the industry the maximum flexibility to decide how best

to meet such standards. It does not intend to regulate or prescribe how the standards are to be met.").

¶ 36 Thus, the potential success of the claims asserted here against Excel because of its alleged failure to reach the goal of non-detectable E. coli contamination set by the Food Safety and Inspection Service is not a "requirement" either "in addition to, or different than" requirements established under the Meat Inspection Act "with respect to premises, facilities and operations"; rather, it is wholly consistent with the predominant intent of the Act, which is to keep health-threatening meat out of the commerce stream. Therefore, the state claims are adjunct to, rather than a displacement of, the standards enacted by Congress and the conforming regulations promulgated by the Secretary. Permitting assertion of those claims supplements, in a way consistent with the "touchstone" of Congressional intent, the federal goal to remove pathogen-laden meat from the food supply.

¶ 37 The record here demonstrates in a concrete way how the claims asserted against Excel supplement protection afforded by the meat-inspection program and what the Food Safety and Inspection Service has recognized are the significant limitations of the "organoleptic examination by inspectors." *Id.* at 38838. Only two federal inspectors oversee a meat fabrication area in Excel's plant where several hundred workers daily cut the approximately seven-foot-long, 350-pound split carcasses into some 8,000 intact cuts of beef weighing approximately two to four or three to five pounds each. Federal inspectors do not inspect each one of these smaller cuts of beef. Moreover, the seven-foot-long carcasses arrive at the fabrication area after whizzing by the Service inspection station at the rate of one side every six seconds.

¶ 38 In sum, since, the "'purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic,* 518 U.S. at 485, 116 S.Ct. 2240 (quoted source omitted), and since the claims asserted against Excel are wholly congruent with the

overarching purpose of the Meat Inspection Act, and in light of the savings clause, which, as we have seen, permits states to "make [ ] requirement[s] or tak[e] other action, *consistent* with [the Act], with respect to any other matters regulated under this [Act]" (emphasis added), we hold that those claims are not preempted by the express-preemption clause in 21 U.S.C. § 678.[7]

B.

¶ 39 As noted, "ordinary" preemption principles may bar state claims even though those claims are not expressly preempted by the applicable federal statute. *Geier,* 529 U.S. at 869, 120 S.Ct. 1913. The prerequisite to finding an implied preemption, however, is "an actual conflict with a federal objective." *Id.,* 529 U.S. at 871, 120 S.Ct. 1913. As already explained at some length, there is no "actual conflict" here; permitting claims against Excel for putting into the stream of commerce meat that was contaminated with E. coli O157:H7 is consistent with the objective of the Meat Inspection Act--the sale in interstate commerce of safe, wholesome meat. Accordingly, there is no implied preemption. *See Sprietsma,* 123 S.Ct. at 522-523.

V.

¶ 40 There are two final matters we must discuss.

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[7] During oral argument, Excel forcefully contended that a failure to apply federal preemption will subject the meat-processing industry to intractable dilemmas. But all manufacturers confront difficult cost/benefit choices when balancing expense and methods of production on the one hand, against, on the other hand, potential liability for injuries that may be caused by their products; we see no special burden on Excel or other meat processors beyond that faced by anyone who puts potentially dangerous products into the stream of commerce.

A.

¶ 41 Excel's briefs rely heavily on *Boulahanis v. Prevo's Family Market, Inc.*, 230 Mich.App. 131, 583 N.W.2d 509 (1998), *cert. denied,* 530 U.S. 1203, 120 S.Ct. 2194, 147 L.Ed.2d 232, which held that the Meat Inspection Act preempted state claims for a death and injuries caused by the sale of ground beef contaminated with E. coli O157:H7. The trial court also relied heavily on *Boulahanis* in deciding to grant summary judgment to Excel. Accordingly, we now turn to that case, which, in our view, is irrelevant to our decision.

¶ 42 In *Boulahanis,* the contaminated meat was purchased in 1993, before the United States Department of Agriculture determined that the E. coli bacterium was dangerous. *Id.*, 583 N.W.2d at 512. The plaintiffs contended that their claims could not be preempted because the Department had not promulgated any regulations concerning the sale of E. coli-infected meat when the meat was purchased, and thus there could be no "conflict with then-existing federal law." *Ibid. Boulahanis* rejected that argument, holding that the Department's "intentional decision not to regulate the presence of E. Coli because it was not considered an adulterant carries the force of positive enactment." *Ibid.* Thus, under *Boulahanis's* view, holding the "defendants liable for failing to detect the presence of E. Coli bacteria in the meat purchased by plaintiffs in 1993 would run contrary to the [Department]'s then-existing determination that inspection for E. Coli bacteria was not required." *Ibid.*

¶ 43 Aside from its other infirmities, including its paucity of analysis, *Boulahanis's* rationale for finding preemption — agency *in* action — is, without a deeper analysis than *Boulahanis* made, questionable in light of *Sprietsma,* which held that although agency inaction could be evidence of a federal mandate to leave an area unregulated, it also could be, and was held in *Sprietsma* to be, "fully consistent with an intent to preserve state regulatory authority pending the adoption of

specific federal standards." *Sprietsma,* 123 S.Ct. at 527-528. Moreover, contrary to the situation in *Boulahanis,* the Food Safety and Inspection Service is now not only concerned with E. coli O157:H7, but, indeed, is striving to reduce its presence in meat sold as human food to, as we have seen, "undetectable levels." *Boulahanis* gives us no guidance.

B.

¶ 44 Although it is hardly dispositive, for the reasons we explain below, the Food Safety and Inspection Service has assumed that tort claims against meat processors are *not* preempted by the Meat Inspection Act.

¶ 45 As we have seen, the Service issued a lengthy report dated July 25, 1996, which explained its proposed Hazard Analysis and Critical Control Point plan and set out proposed implementing rules. The report also noted concerns expressed by some of those with whom it had consulted. Responding to a concern raised by "[a] few commenters . . . about product liability due to product recalls stemming from test results," the Service explained: "Establishments' liability to civil lawsuits should not be adversely affected by this rule precisely because it is an establishment's process, not individual lots of product, that is being assessed, for inspection purposes, on the basis of this testing." PATHOGEN REDUCTION, 61 FED.REG. at 38854. Moreover, the Service opined that if meat producers "did not suffer legal consequences" as a result of selling pathogen-infested meat, it was because "[c]onsumers often cannot trace a transitory illness [caused by pathogenic microorganisms] to any particular food or even be certain it was caused by food." *Ibid.*

¶ 46 Nowhere in the July 25, 1996, report did the Service even hint that it considered tort claims against meat processors to be preempted by the Meat Inspection Act, and we are aware of no other place where it has so opined. We mention all this in passing, however, because it is far from settled that an agency's view of the preemptive effect of a statute is given *any*

deference. Indeed, the United States Supreme Court has assumed that the agency's view is entitled to *no* deference. *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 744, 116 S.Ct. 1730, 135 L.Ed.2d 25 (1996) (assuming, but not deciding, that "whether a statute is pre-emptive . . . must always be decided *de novo* by the courts"). *See also Commonwealth of Massachusetts v. United States Dep't of Transp.*, 93 F.3d 890, 892-897 (D.C.Cir.1996) (recognizing *Smiley*, discussing deference to the agency and holding contrary to the agency's view).

VI.

¶ 47 We reverse the summary judgments granted to Excel dismissing the claims of the Kriefalls, the Lesaks, the Fortiers, the McCormicks, and Sizzler USA.[8]

By the Court. — Judgments reversed.

---

[8] In light of our holding that the claims asserted against Excel are not preempted by federal law, we do not address the additional argument that Excel waived by contract its right to rely on the preemption doctrine. *See Gross v. Hoffman*, 227 Wis. 296, 300, 277 N.W. 663, 665 (1938) (only dispositive issue need be addressed); *State v. Blalock*, 150 Wis.2d 688, 703, 442 N.W.2d 514, 520 (Ct.App.1989) (cases should be decided on the "narrowest possible ground").

COURT OF APPEALS
OF WISCONSIN
OFFICE OF THE CLERK
110 EAST MAIN STREET, SUITE 215
P. O. Box 1688
MADISON, WISCONSIN 53701-1688
Telephone: (608) 266-1880
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CORNELIA G. CLARK
CLERK

REMITTITUR Date: September 12, 2003

District 1
Case No. 02-1939
Circuit Court Case No. 00 CV 6463, 00 CV 6360, 00 CV 8756, 00 CV 8793

Estate of Brianna L. Kriefall, deceased, by her Special Administrator, Douglas A. Kriefall, Douglas A. Kriefall, Connie J. Kriefall, and Chad Kriefall, a minor, by his Guardian ad Litem, William M. Cannon,
Plaintiffs-Appellants,
Humana Employers Health Insurance Co., a Wisconsin insurance corporation,
Involuntary-Plaintiff,

v.

Sizzler USA Franchise, Inc., a foreign corporation,

Defendant-Third-Party Plaintiff-Co-Appellant,

Federal Insurance Co., a foreign insurance corporation, E&B Management Co. Waukesha, Inc., a Wisconsin corporation, Secura Insurance, a Wisconsin insurance corporation, Sysco Services of Eastern Wisconsin, a wholly owned subsidiary of Sysco Corporation, a foreign corporation, Fidelity and Guaranty Insurance Co., a foreign insurance corporation, Lee M. Eschenbach, Steven C. Boysa, AAA Insurance Co., and BBB Insurance Co.,

Defendants,

Excel Corporation, a foreign corporation, and American Home Assurance Co., a foreign insurance corporation,

Defendants-Respondents,

v.

Lee M. Eschenbach, Steven C. Boysa, AAA Insurance Co., BBB Insurance Co., Cargill, Inc., a foreign corporation, and Excel Food Distribution, Inc., a foreign corporation,

Third-Party Defendants.

Ervin J. Lesak and Florence Lesak,

Plaintiffs-Co-Appellants,

v.

E&B Management Co. Waukesha, Inc.,

Defendant,

Excel Corporation,
Defendant-Respondent.

Jeffrey Fortier, Judith Fortier, Tristan Fortier,
and Carly Fortier,
Plaintiffs-Co-Appellants,
Great West Life & Annity Insurance,
Involuntary-Plaintiff,

v.

Excel Corporation,
Defendant-Respondent.

Kevin McCormick, Sandy McCormick, and
Kelsea McCormick,
Plaintiffs-Co-Appellants,
Blue Cross Blue Shield United,
Involuntary-Plaintiff,

v.

Excel Corporation,
Defendant-Respondent.

John Barrett, Circuit Court Clerk
Appeals Processing Division
901 N. 9th Street, Room G-8
Milwaukee, WI 53233

Daniel J. Brown
Dorsey & Whitney, LLP
50 South Sixth Street, Suite 150
Minneapolis, MN 55402-1490

Frederic Gordon
Gordon & Holmes
1230 Columbia St., # 700
San Diego, CA 92101

William M. Cannon
Cannon & Dunphy, S.C.
P.O. Box 1750
Brookfield, WI 530008-1750

James R. Gass
Kravit, Gass, Hovel & Leitner, S.C.
825 North Jefferson
Milwaukee, WI 53202-3737

Beth Kushner
von Briesen, Purtell & Roper, S.C.
735 North Water St., Ste. 1000
Milwaukee, WI 53202

Mark M. Leitner
Kravit, Gass, Hovel & Leitner, S.C.
825 North Jefferson, # 500
Milwaukee, WI 53202-3737

James W. Mohr, Jr.
Mohr & Anderson, LLC
23 S. Main Street
Hartford, WI 53027

David J. Roettgers
Weiss, Berzowski, Brady
700 Water Street, Ste. 1500
Milwaukee, WI 53202

Ralph A. Weber
Reinhart, Boerner, Van Deuren, S.C.
P.,O. Box 2965
Milwaukee, WI 53201-2965

Ronald G. Pezze, Jr.
Peterson, Johnson & Murray
733 North Van Buren Street
Milwaukee, WI 53202

Thomas H. Koch
Law Offices of Thomas H . Koch
3466 South 13th Street
Milwaukee, WI 53215

Russell A. Klingaman
Hinshaw & Culbertson
100 East Wisconsin Ave., # 2600
Milwaukee, WI 53202-4115

Michael J. Hanrahan
Fox, Carpenter, O'Neill & Shannon
622 N. Water St., # 600
Milwaukee, WI 53202-4909

Denis W. Stearns
Marler Clarka LLP PS
4301 Bank of America Tower, 701 5th Avenue
Seattle, WA 98104-7016

Amelia L. McCarthy
Reinhart Boerner, Van Deuren, S.C.
P.O. Box 2965
Milwaukee, WI 53201-2965

Edward E. Robinson
Cannon & Dunphy, S.C.
P.O. Box 1750
Brookfield, WI 53008-1750

Amy E. Wochos
Piper & Schmidt
733 N. Van Buren Street, 5th Floor
Milwaukee, WI 53202-4709

Thomas Gonzalez
Kravit, Gass, Hovel & Leitner, S.C.
825 North Jefferson
Milwaukee, WI 53202-3737

Shawn K. Stevens
Reinhart, Boerner, Van Deuren, S.C.
P.O. Box 2965
Milwaukee, WI 53201-2965

Timothy A. Bascom
Bascom, Budish & Ceman, S.C.
2600 North Mayfair Rd., # 1140
Milwaukee, WI 53226

This cause was an appeal to review the judgment(s) and order(s) of the Circuit Court of Milwaukee County.

IT IS ORDERED AND ADJUDGED by this court in an opinion filed on May 13, 2003, that:

Judgments reversed.

Panel: Hon. Ralph Adam Fine
Hon. Charles B. Schudson
Hon. Michael W. Hoover

The appeal record is hereby returned to the Clerk of the Circuit Court for Milwaukee County.

I certify that the above is a correct transcript of the original order and judgment of the court in the above cause.

Cornelia G. Clark
Clerk of Court of Appeals

OFFICE OF THE CLERK
SUPREME COURT OF WISCONSIN
110 EAST MAIN STREET, SUITE 215
P.O. BOX 1688
MADISON, WISCONSIN 53701-1688
TELEPHONE: 608-266-1880
FACSIMILE: 608-267-0640
Web Site: www.wicourts.gov

September 12, 2003

To:

Hon. Michael P. Sullivan
Milwaukee County Circuit Court
901 N. Ninth Street
Milwaukee, WI 53233

John Barrett
Milwaukee County Clerk of Courts
Appeals Processing Division
901 N. Ninth Street, Room G-8
Milwaukee, WI 53233

J. Ric Gass
Mark M. Leitner
Thomas Gonzalez
Kravit, Gass, Hovel & Leitner, S.C.
825 North Jefferson, # 500
Milwaukee, WI 53202-3737

Daniel J. Brown
Dorsey & Whitney, LLP
50 S. Sixth Street, Suite 105
Minneapolis, MN 55402-1490

Frederic Gordon
Gordon & Holmes
1230 Columbia Street, # 700
San Diego, CA 92101

William M. Cannon
Edward E. Robinson
Cannon & Dunphy, S.C.
P.O. Box 1750
Brookfield, WI 53008-1750
(Additional Addresses on Page Two)

You are hereby notified that the Court has entered the following order:

No. 02-1939 Estate of Brianna L. Kriefall v. Sizzler U SA, et al., L.C. #s 00CV6463, 00CV6360, 00CV8756, 00CV8793

A petition for review pursuant to Wis. Stat. § 808.10 having been filed on behalf of defendant-respondent-petitioner, Excel Corporation, and a motion of the American Meat Institute, et al. for permission to file an *amicus curiae* brief, and considered by this court;

IT IS ORDERED that the motion is granted and the *amicus curiae* brief is accepted for filing.

IT IS FURTHER ORDERED that the petition for reveiw is denied, with $50 costs to be divided equally among respondents.

Wilcox, J., did not participate.

Cornelia G. Clark
Clerk of Supreme Court

Additional Addresses:

Beth Kushner
von Briesen, Purtell & Roper, S.C.
735 N. Water Street, Suite 1000
Milwaukee, WI 53202

James W. Mohr, Jr.
Mohr & Anderson, LLC
23 S. Main Street
Hartford, WI 53027

David J. Roettgers
Weiss, Berzowski, Brady
700 N. Water Street, Suite 1500
Milwaukee, WI 53202

Ralph A. Weber
Amelia L. McCarthy
Shawn K. Stevens
Reinhert Boerner Van Deuren S.C.
P.O. Box 2965
Milwaukee, WI 53201-2965

Ronald G. Pezze, Jr.
Peterson, Johnson & Murray
733 North Van Buren Street
Milwaukee, WI 53202

Thomas H. Koch
Law Offices of Thomas H. Koch
3466 South 13th Street
Milwaukee, WI 53215

Michael J. Hanrahan
Fox, Carpenter, O'Neill & Shannon
622 N. Water Street, # 600
Milwaukee, WI 53202-4909

Denis W. Stearns
Marler Clarka LLP PS
701 5th Avenue, 4301 Bank of America Tower
Seattle, WA 98104-7016

Amy E. Wochos
Piper & Schmidt
733 N. Van Buren Street, 5th Floor
Milwaukee, WI 53202-4709

Timothy A. Bascom
Bascom, Budish & Ceman, S.C.
2600 North Mayfair Road #1140
Milwaukee, WI 53226

STATE OF WISCONSIN
CIRCUIT COURT, MILWAUKEE COUNTY
Re: In re Consolidated *E. coli* 0157:H7 Cases
Case Nos. 00-CV-006503
00-CV-006327
00-CV-006422
00-CV-006367
00-CV-006466
00-CV-006437
00-CV-006412
00-CV-008756
00-CV-008793
00-CV-006360
00-CV-006463

DECISION ON EXCEL CORPORATIONS

MOTION FOR SUMMARY JUDGMENT

Excel Corporation ("Excel"), the meat processor defendant in the above cases, moves for summary judgment of dismissal of plaintiffs claims against it. I grant Excel's motion for two reasons. First, I agree with Excel that Congress has delegated to the USDA the exclusive role of determining when meat is safe and unadulterated. Second, Excel has not contractually waived its federal preemption arguments as to the plaintiffs' claims.

For roughly one hundred years in this country, Congress has regulated the distribution of meat products in interstate commerce. This is the direct legacy of muckrakers like Upton Sinclair, the author of *The Jungle*. Sinclair, a socialist, was said to have lamented later in life that he aimed his novel at America's heart, but instead hit her in the stomach. His novel vilified the meat industry in this country and helped bring about reforms that resulted in the extensive regulatory scheme present in our country today. Congress has delegated that regulatory role to the USDA. See 21 U.S.C. sec. 601 *et seq.* Part of the

USDA's job is to determine when meat is "safe, wholesome, and not adulterated." *Armour & Co. v. Ball*, 468 F.2d 76, 81 (6th Cir., 1972). Intact meat containing surface E coli 0157:H7 bacteria is not considered adulterated under federal law because the bacteria is destroyed when the surface of the intact cuts are broiled in establishments like Sizzler's Steak House. See 64 Fed. Reg. 2803, 2804 (1999).

> "Intact steaks, and other intact cuts of muscle with surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with E. coli 0157:H7 when consumed. Consequently, such intact products that are to be distributed for consumption as intact cuts are not deemed adulterated."

Congress has expressly preempted the states from establishing meat standards different from the federal ones. 21 U.S.C. sec. 678 states:

> "Requirements . . . with respect to premises, facilities and operations of any establishment . . . which are in addition to, or different than those made under this chapter may not be imposed by any State . . . Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State . . ."

This express preemption provision overcomes any state law to the contrary. *Boulahanis v. Prevo's Family Market, Inc.*, 583 N.W.2d 509, 511-12 (Mich. App. 1998), cert. denied, 530 U.S. 1203 (1998).

The policy behind preemption in this area makes sense. Excel's processing plant is an "official establishment" governed by the Federal Meat Inspection Act. The federal government has acted in this area to provide national standards so that properly handled and cooked meat products are safe for human consumption. These standards protect the meat processors also, so that they know what is expected of them in regard to their

products that are distribute [sic] among the many states. In an area of such great national concern, it is essential that the rules be uniform. Federal inspectors are in these meat plants, testing the meat and monitoring the processing programs of companies like Excel. The federal regulatory scheme is so long-standing and so comprehensive that I conclude it preempts any state laws to the contrary. That includes bringing civil suits against meat processors like Excel.

Nor did Excel contract away its right to rely on federal preemption. First of all, warranty claims require privity, and the plaintiffs here were not in privity with Excel in the 2000 sale. *Twin Disc, Inc. v. Big Bud Tractor, Inc.*, 582 F. Supp. 208, 215 (E.D. Wisc. 1984). Excel sold its meat to Sysco, who in turn sold it to the franchisee, E&B. Second, Sysco's purchase of the meat in question was governed by an agreement dated January 11, 2000. That agreement contained a clause stating that the document ". . . contains the entire agreement between the parties and cannot be varied orally and sh all be binding on the heirs, successors and assigns of the parties." This "merger clause" effectively does away with the 1993 and 1997 "contracting away" documents relied on by the opposition to the motion.

It is important to note that this decision does not deny these plaintiffs their day in court. They may continue to proceed against the restaurant whose employees handled the food as well as against the restaurant's national franchisor, who is alleged to have improperly trained and supervised it[s] local franchisee. But they may not sue Excel.

Counsel for the prevailing party shall prepare and submit the appropriate under the local five-day rule.

Dated: May 15, 2002.

By the Court:

/s/Michael P. Sullivan
Michael P. Sullivan
Circuit Judge

STATE OF WISCONSIN
CIRCUIT COURT, MILWAUKEE COUNTY

In re Consolidated *E. coli* 0157:H7 Cases
Case Nos. 00-CV-006503
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00-CV-006412
00-CV-008756
00-CV-008793
00-CV-006360
00-CV-006463

Case Code. 30107 - Personal Injury, Other

ORDER GRANTING
EXCEL CORPORATION'S
MOTION FOR SUMMARY JUDGMENT

This matter came before the Court on Excel Corporation's Motion for Summary Judgment seeking to dismiss plaintiffs' claims against Excel Corporation as a matter of law. The Motion was fully briefed, and argued on March 25, 2002.

The Court considered the written submissions and oral arguments. For the reasons set forth in the Court's May 15, 2002 written Decision on Excel Corporation's Motion for Summary Judgment, plaintiffs' claims fail as a matter of law.

Further, the effect of the Court's May 15, 2002 written Decision requires the dismissal of the cross-claims asserted by Sizzler USA Franchise Inc. against Excel Corporation and its business unit, Excel Food Distribution Company.

THEREFORE, IT IS ORDERED that Excel Corporation's Motion for Summary Judgment is GRANTED, and judgment is hereby rendered in favor of Excel Corporation on plaintiffs'

claims. Plaintiffs' claims against Excel Corporation are hereby dismissed with prejudice.

IT IS FURTHER ORDERED that Sizzler USA Franchise Inc.'s cross-claims asserted against Excel Corporation and its business unit, Excel Food Distribution Company are hereby dismissed with prejudice.

Dated at Milwaukee, Wisconsin this 19th day of June, 2002.

/s/ Michael P. Sullivan
Michael P. Sullivan
Circuit Court Judge

STATE OF WISCONSIN
CIRCUIT COURT, MILWAUKEE COUNTY

In re Consolidated *E. coli* 0157:H7 Cases
Case Nos. 00-CV-006503
00-CV-006327
00-CV-006422
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00-CV-006437
00-CV-006412
00-CV-008756
00-CV-008793
00-CV-006360
00-CV-006463
Case Code: 30107 - Personal Injury, Other

JUDGMENT

Pursuant to the Court's Order dated June 19, 2002;

IT IS HEREBY ADJUDGED THAT:

1. Excel Corporation's Motion for Summary Judgment is granted and judgment is entered in favor of Excel Corporation on plaintiffs' claims. Plaintiffs' claims against Excel Corporation are dismissed with prejudice.

2. Sizzler USA Franchise Inc.'s cross-claims asserted against Excel Corporation and its business unit, Excel Food Distribution Company are dismissed with prejudice.

Judgment entered July 16, 2002.

By the Court
John Barrett
Clerk of Circuit Court
By /s/Diane Gawronski
Judgment Clerk

21 U.S.C. § 601. **Definitions**

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

* * *

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
>
> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;
>
> (B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,
>
> (C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: Provided, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been

substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

21 U.S.C. § 602. **Congressional statement of findings**

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwhclesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

21 U.S.C. § 621. **Inspectors to make examinations provided for; appointment; duties; regulations**

The Secretary shall appoint from time to time inspectors to make examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines, inspection of which is hereby provided for and of all carcasses and parts thereof, and of all meats and meat food products thereof, and of the sanitary conditions of all establishments in which such meat and meat food products hereinbefore described are prepared; and said inspectors shall refuse to stamp, mark, tag, or label any carcass or any part thereof, or meat food product therefrom, prepared in any establishment hereinbefore mentioned, until the same shall have actually been inspected and found to be not adulterated; and shall perform such other duties as are provided by this chapter and by the rules and regulations to be prescribed by said Secretary; and said Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter, and all inspections and examinations made under this chapter, shall be such and made in such manner as described in the rules and regulations prescribed by said Secretary not inconsistent with provisions of this chapter.

21 U.S.C. § 678. **Non-Federal jurisdiction of federally regulated matters; prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters**

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

U.S. Department of Agriculture
Food Safety and Inspection Service
Boulder District Office
665 S. Broadway, Suite B
Boulder, CO 80303
Telephone: (303) 497-5411
Facsimile: (303) 497-7306

August 25, 2000

Marsha Kreegar
Regulatory Affairs Superintendent
1505 Burlington Avenue
Fort Morgan, Colorado 80701

Dear Ms. Kreegar:

I received your request dated July 28 2000 to reduce carcass testing for E. coli O157:H7. Because of recent events involving zero tolerance and another confirmed positive for E. coli O157:H7 I am unable to approve your request. Although E. coli O157:H7 is not considered an adulterant in whole muscle cuts at this time, it is our suggestion that your HACCP plan be reassessed. Please let me know about your decision in this matter by September 1, 2000 and if you decide to reassess on what date the reassessment will be completed.

If you have any questions, please call me.

Sincerely,

/s/ Ronald J. Jones
Ronald K. Jones, District Manager

cc: Dr. Dale Hansen
Dr. Michael Finley
Scott Goltry, Excel Corporation

United Sates Department of Agriculture
Office of Public Affairs
News Division
Room 404-A
Washington, D.C. 20250

News Release No. 0092.93

Testimony

by

DR. H. RUSSELL CROSS
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture

Before the State of Washington
Senate Committee on Agriculture

February 2, 1993

Madam Chairwoman. I am Dr. H. Russell Cross, Administrator of the U.S. Department of Agriculture's Food Safety and Inspection Service. With me is my assistant, Dr. Jill Hollingsworth. We very much appreciate the opportunity to be here today.

Before I begin, I want to reinforce the comments made by the secretary. We send our condolences to all family and friends affected by this tragedy. I also want you to know that the employees of FSIS are committed to pursuing every avenue to identify, contain and resolve this E. coli outbreak.

First, I will discuss what FSIS does. This agency is charged with inspecting meat and poultry products distributed in commerce to ensure they are safe and accurately labeled. FSIS carries out these inspections under the authority of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

We have 7,000 employees located throughout the United States inspecting meat and poultry. If a meat or poultry product is to be prepared at federally inspected establishments and/or distributed in commerce, an FSIS inspector inspects that product. Under the FMIA and the PPIA, we inspect the live animals before slaughter, and we inspect the carcasses after slaughter. Approximately 19 different inspection tasks are performed on each meat carcass.

As of the end of Fiscal Year 1991, 6,400 meat and poultry slaughtering and processing establishments received daily federal inspection. Over 117 million meat animals and over 6 billion birds were federally inspected during that year. Of the meat animals inspected during FY91, approximately 386,000 carcasses, or 1/3 of 1 percent, were condemned. For poultry, 75 million birds were condemned, or just over 1 percent. Carcasses are condemned for disease, contamination, or other adulteration during inspection.

Inspections of imported meat and poultry from approved countries are also performed by FSIS at 210 import inspection establishments located at borders or ports. In 1991, approximately 2.5 billion pounds of imported meat and poultry were passed for entry into the United States. Approximately 12 million pounds, or less than 1 percent of imported product, were refused entry to the U.S. due to failure to meet Federal requirements.

Another part of our food safety program involves laboratory analysis. Inspectors in the field are supported by laboratory testing for chemical and antibiotic residues, pathology diagnostics, processed product composition, and economic adulteration. We also analyze cooked meat and poultry products for microbiological contamination.

To conduct these laboratory analyses, FSIS operates three multidisciplinary laboratories and two contract laboratories, and accredits 215 private laboratories. We also have laboratories located at the Beltsville Agriculture Research Center, which are

methods development laboratories in pathology and microbiology. During Fiscal Year 1991, over 2.1 million analyses were performed on 470,573 samples at a cost of approximately $8.5 million.

Rapid in-plant screening tests provide another measure of safety. Results from these tests are available very quickly, thus assisting inspectors in making rapid food safety determinations about the product. Regrettably, there is no in-plant test developed and approved for microbiological testing of raw meat and poultry products. This is one of our highest research priorities and we expect significant progress in this area in the future.

FSIS also conducts enforcement and compliance activities to ensure that meat and poultry products in commerce are not adulterated, and are accurately labeled. In FY91, 63,416 compliance reviews were conducted. As a result of these reviews and other compliance activities, over 16 million pounds of meat and poultry were detained for noncompliance with meat and poultry laws. Twenty-nine recalls were conducted involving over 1.8 million pounds of product. In addition, 35 convictions were obtained against firms and individuals for violations of the FMIA and the PPIA.

The definition of "adulterated" under the meat and poultry acts has been construed by the Court of Appeals for the District of Columbia in American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974). In that case, the Court held that the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation. The Court has stated that Congress did not intend the prescribed official inspection legends on meat and poultry products to mean that the products were free from salmonellae and other bacteria because Congress did not intend that inspections include "microscopic examinations."

For this reason, raw meat with pathogens, even this product with E. coli 0157:H7, is not considered adulterated. Our review

and investigation have shown that all of the meat implicated in this outbreak was inspected and met the federal criteria for "safe raw meat." The bottom line is that raw meat contains bacteria, but proper cooking kills bacteria.

Although FSIS doesn't routinely perform microbiological tests on raw meat and poultry products, we have begun a baseline data collection program. However, as I have stated, products inherently contain bacteria, which does not cause them to be adulterated under the law.

Even if our statutes were changed, science is not advanced enough to make rapid microbiological testing feasible. Nor does a sample give a true picture of all the product – it is not possible to know if the "right" product has been sampled unless everything is sampled.

The simple fact is that proper cooking of meat and poultry products kill harmful bacteria. Cooking for the proper amount of time and at the State-mandated temperature would have prevented this outbreak.

As you might imagine, however, simply saying "cook meat and poultry properly" is not a satisfactory answer. Although the inspection system did not fail, we want to do more. We will be working with the U.S. Congress to develop intermediate and long term strategies that will ultimately take us to an inspection system that takes advantage of emerging technology and focuses on the various risks found in meat and poultry – including microbiological contaminants.

For the purposes of this hearing, I would like to focus on what we know today, what we can do today, and what we've already done.

FSIS was first notified by the Centers for Disease Control (CDC) of an outbreak of E. coli 0157:H7 in Washington State on January 18. In addition to immediately establishing a liaison with CDC, we contacted the State of Washington Department of Public Health to offer our assistance. We recognize that the

Department of Public Health has the lead in this investigation, but we have offered our assistance in conducting microbiological testing and in exercising our authority in federally inspected meat plants that might be involved. We also made contact with laboratories and individuals identified by CDC as playing a role in this investigation. The Washington Department of Public Health traced the most likely source of the bacteria to undercooked hamburger patties served at Jack-in-the-Box restaurants.

The production date of November 19, 1992, has been implicated by the State of Washington as the product used by Jack-in-the-Box that contained E. coli 0157:H7. It has a "use by" date of March 19, 1993. We requested that all product marked with this "use by" date be held by the parent company of Jack-in-the-Box, Foodmaker. That day's production continues to be held and has been the subject of microbiological testing by the State of Washington, USDA, and CDC. Should any other production date be implicated, we will hold that product also.

On January 19, we sent a team of FSIS Compliance Officers to a warehouse owned by Foodmaker in Tukwila, Washington, which was identified as the distributor of hamburger patties to Jack-in-the-Box. Compliance Officers were on site to monitor the return of product to the warehouse from Jack-in-the-Box and to ensure that the hamburger patties were properly detained in freezers. As soon as we learned that product was also being returned to another Foodmaker warehouse in the City of Commerce, California, we also sent our Compliance Officers there to monitor the product detention.

FSIS Compliance Officers have also been in touch with other state departments of health in states where the suspect product has been distributed. This includes the states of California, Nevada, Utah, Idaho, and Hawaii.

As you all know by now, the raw patties distributed by Foodmaker were produced at Vons Meat, a federally inspected

establishment in El Monte, California. Vons grinds the meat and makes the patties for Foodmaker. For November 19, 1992, we have been told all the product went to Foodmaker.

FSIS has dispatched a microbiologist and an epidemiologist to Vons to collect environmental and product samples. We also have sent FSIS Inspection Operations personnel to Vons to examine records and trace back possible sources of meat Vons used in its production. The samples we have collected from Foodmaker represent the production lots produced at Vons on November 19, 1992.

FSIS has confirmed laboratory results from 4 of the sampled lots. The actual number of bacteria found have been relatively low. We are continuing our lab tests and will conduct well over 1,000 analyses.

The positive test results from the November 19 product from Vons now leads our investigation to the plants that supplied meat to Vons, not only on November 19, but from October 1, 1992, to the present. It is difficult to recreate conditions and events that existed on November 19, but we are checking records to see if we can further track implicated product, trying to determine where the bacteria came from and how it got into the product.

For each supplier of Vons, we have sent Inspection Operations personnel to examine current sanitation records and general operating procedures. We are also focusing on the records of each of the suppliers to see if any breakdown in normal procedures occurred around the suspect date.

In addition, microbiologist teams will be taking samples from every supplier plant. At these supplier plants, we will be performing product sampling in addition to record checks. As with Vons, it is very difficult to recreate conditions as they existed months ago at these plants, but we want to cover every base possible.

While we continue our investigation on all fronts, there are other things FSIS is doing. We will expand our microbiological baseline data collection in beef animals. This survey will be ongoing. Results will give us the opportunity to establish the kind and amount of bacteria that are present today, and to determine if future changes in inspection procedures improve the microbiological profile of the carcasses.

We have held briefings for consumer and trade groups and Congressional staffers to make them aware of this outbreak and to let them know of the steps we are taking to end it. We have issued numerous consumer publications on how to safely cook, handle and store meat and poultry products. We are happy to make those available to anyone needing this type of information. We also operate a toll free Meat and Poultry Hotline that is staffed by home economists who answer basic or technical questions about food safety. Our Hotline number is 1-800-535-4555.

Although most of our inspectors and indeed most of our employees know of this E. coli outbreak, we issued an alert to all inspectors yesterday calling their attention to possible sources of this bacteria. Specifically, we are asking our inspectors to review all operations and procedures at the establishments they inspect to ensure that we are doing everything we can.

Additionally, the National Advisory Committee for Microbiological Criteria for Foods is meeting today. This Committee was formed in 1988, and has been extremely helpful to FSIS and the Secretary in making recommendations on controlling bacteria in the food supply. In light of this current outbreak, we have asked the Committee to take up the topic of E. coli 0151:H7 at its meeting today.

Other educational work on E. coli 0157:H7 is ongoing. It is frustrating to realize how little is really known about this pathogen. We are identifying experts and researchers to determine if there is any new scientific information available.

We are working with our sister agency, the Animal and Plant Health Inspection Service, to ascertain what information it might have about the occurrence of E. coli 0157:H7 in animals on the farm.

We do know that the group of bacteria called Escherichia coli are normally found in the intestines of warm-blooded animals such as food animals or humans. It can be found in contaminated water, and raw milk. It is not known at what level or dose the pathogen becomes hazardous.

In 1982, a rare and more virulent strain, called E. coli 0157:H7, was identified as the cause of two outbreaks of human illness. Since that time, there have been other reported outbreaks. Sources of E. coli 0157:H7 have included raw meat, water, unpasteurized milk, and low-acid apple cider.

E. coli 0157:H7 does not cause illness in animals. It can be carried in the intestinal tract of an animal, although it can also be found on the animal from contact with feces, and in the milk of dairy cows. Animals carrying this bacteria appear normal at the time of FSIS inspection, which is performed on each and every carcass. We do not know if the bacteria can be found elsewhere, such as circulating in the blood or lymphatic system. It can be transferred to the meat from the feces or milk. If there is any visible contamination on the meat, FSIS requires its removal. Also, all carcasses are thoroughly washed after inspection.

I cannot adequately express how distressed we in FSIS are that these tragic deaths and illnesses have occurred. But the fact is: bacteria, including pathogens, can be found on raw meat. This product is not adulterated. Science is not advanced enough to permit us to rapidly identify or control microbiological contaminants on raw meat, but E. coli 0157:H7 can be controlled by thorough cooking of raw meat.

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No. 03-862

IN THE

Supreme Court of the United States

EXCEL CORPORATION,
Petitioner,

v.

ESTATE OF BRIANNA L. KRIEFALL, *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

BRIEF FOR RESPONDENTS IN OPPOSITION

RUSSELL A. KLINGAMAN
HINSHAW & CULBERTSON
100 E. Wisconsin Avenue
Milwaukee, WI 53202
(414) 276-6464

WILLIAM D. MARLER
DENIS W. STEARNS
MARLER CLARK, LLP, PS
4301 Bank of America Tower
701 Fifth Avenue
Seattle, WA 98104
(206) 346-1888

WILLIAM M. CANNON
EDWARD E. ROBINSON
CANNON & DUNPHY, S.C.
595 North Barker Road
Brookfield, WI 53008
(262) 787-2700

H. BARTOW FARR, III
FARR & TARANTO
1220 19th Street, N.W.
Suite 800
Washington, D.C. 20036
(202) 775-0184

FREDERIC L. GORDON
Counsel of Record
RHONDA J. HOLMES
GORDON & HOLMES
1230 Columbia Street
Suite 700
San Diego, CA 92101
(619) 696-0444

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTIONS PRESENTED

1. Whether this Court has jurisdiction under 28 U.S.C. § 1257(a) to review a decision of a state court when reversal on the federal issue would not benefit petitioner and when other substantial issues would nonetheless remain to be resolved in further state-court proceedings.

2. Whether the state court of appeals was required to defer to a policy statement by the United States Department of Agriculture when the policy statement was inconsistent with the terms and purposes of the Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, and with other pronouncements and directives of the Agency itself.

RULE 29.6 STATEMENT

Respondent Sizzler USA Franchise, Inc. is a wholly owned subsidiary of Sizzler USA, Inc., which is a wholly owned subsidiary of Worldwide Restaurant Concepts, Inc., a publicly held company.

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BRIEF FOR RESPONDENTS IN OPPOSITION

STATEMENT

This case arises out of several consolidated state-law tort suits involving persons who became ill—and, in one case, died—after consuming food contaminated with the pathogen E. coli O157:H7. The source of the contamination was meat processed at a plant operated by petitioner Excel Corporation.

A. Federal Meat Inspection And The USDA Treatment of E. coli O157:H7.

The E. coli O157:H7 bacterium is a highly dangerous source of foodborne illness. "Exposure to E. coli O157:H7 has been linked with serious, life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome)." 64

Fed. Reg. 2803 (Jan. 19, 1999). Moreover, unlike many other microorganisms, E. coli O157:H7 constitutes a serious threat to public health even at relatively low levels. As the Department of Agriculture (USDA) has said, "[s]ome pathogens, such as E. coli O157:H7, are so virulent that a small number of organisms can pose a significant hazard." 61 Fed Reg. 38,806, 38,835 (July 25, 1996).[1] For that reason, "any amount of E. coli O157:H7 will adulterate a meat or poultry product." *Id.*

E. coli O157:H7 is not naturally present in beef meat. Rather, E. coli O157:H7 is found in cattle feces and ingesta, and then transferred to meat through "fecal contamination." 61 Fed. Reg. 38,837. Fecal contamination, in turn, results from improper handling of carcasses during the slaughtering process. *See id.* ("without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans"). The USDA has stated that "[i]n slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens." *Id.*

The virulent E. coli O157:H7 strain of E. coli was first discovered in 1982. Thus, while the Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et. seq.*, has long given the Agency authority to prevent distribution of "adulterated" meat products, *see* 21 U.S.C. § 606, the USDA for years did not identify E. coli O157:H7 as an adulterant.[2] That view

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[1] The USDA exercises many of its responsibilities regarding meat safety through the Food Safety and Inspection Service (FSIS). For simplicity, we generally use the terms "USDA" or "Agency" to refer to actions and declarations by the FSIS in the exercise of its delegated authority.

[2] The term "adulterated" is defined at 21 U.S.C. § 601(m). *See* Pet. App. 55a. Thus, a meat product is considered to be "adulterated" if, for example, "it bears or contains any poisonous or deleterious substance

changed in the early 1990s, however, following serious outbreaks of illness induced by E. coli O157:H7. The USDA subsequently adopted a policy that seeks to eradicate E. coli O157:H7 from meat and poultry products, with a current goal of reducing E. coli O157:H7 "to an undetectable level." *See* 67 Fed. Reg. 62,325, 62,329 (Oct. 7, 2002).

To achieve that goal, the Agency has enacted new rules requiring meat processing facilities to adopt Hazard Analysis and Critical Control Point (HACCP) plans that, among other things, prevent "contamination with fecal material and other intestinal contents . . . ." 61 Fed. Reg. 38,838. It thus has stated that "preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments." 61 Fed. Reg. 38,837. Recognizing that fecal contamination is "largely preventable," *id.*, the Agency requires slaughter establishments to adhere "to zero tolerance for fecal contamination." 61 Fed. Reg. 38,850.

The HACCP system altered USDA's prior program of organoleptic meat and poultry inspection by federal inspectors. Under the pre-HACCP program, every stage of meat production was monitored by USDA employees rather than by in-plant personnel. *See* Pet. App. 21a; USDA. Rep. No. 24001-3-At, at 1 (2000). The HACCP system reversed this arrangement by allowing—indeed requiring—a plant to monitor itself. As a result, the new HACCP rules "gave [the meat] industry, not Government, the primary responsibility for ensuring the safety of meat . . . products." *Id.*

The USDA has also recognized that "[o]ccurence of food-borne disease is a multi-step process." 61 Fed Reg. 38,966. In addressing the problem of dangerous pathogens, therefore,

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which may render it injurious to health" (with an exception for harmless amounts), 21 U.S.C. § 601(m)(1), or if it has been prepared "under insanitary conditions . . . whereby it may have been rendered injurious to health." 21 U.S.C. § 601(m)(4).

it has emphasized in the new HACCP rules that "[t]he first, and critical, step is the introduction of a pathogen into or onto the raw product." *Id.* Once E. coli O157:H7 has contaminated a meat product, it follows that any resulting illness has its roots in the initial flawed treatment. As the USDA has declared, "disease would not have occurred if the pathogen had not been present on the raw product in the first place." *Id.*

In addition to the HACCP rules, the USDA has also addressed the dangers of E. coli O157:H7 in a 1999 policy statement—the statement on which petitioner places almost total reliance in this case—indicating that since 1994 it had generally regarded, and would continue to regard, "non-intact" cuts of meat as "adulterated" if they were contaminated with E. coli O157:H7. *See* 64 Fed. Reg. 2803.[3] The USDA also indicated that, with one narrow exception, it regards "intact cuts" as adulterated when they are contaminated with E. coli O157:H7. *See* 64 Fed. Reg. 2803 ("[t]he public health risk presented by beef products contaminated with E. coli O157:H7 is not limited . . . to raw ground beef products"). In setting forth this policy, the Agency explicitly recognized that, while contamination with E. coli O157:H7 takes place on the surface of intact cuts (and thus is more easily destroyed by cooking), many intact cuts undergo further processing before cooking, either at separate processing plants or at retail establishments. *Id.* That additional processing may include certain methods of tenderizing, as

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[3] The USDA, acting through the FSIS, stated that "[t]his notice explains the Agency's policy governing beef products that contain the pathogen Escherichia coli O157:H7 (E. coli O157:H7)." 64 Fed. Reg. 2803. We thus use the terminology "policy statement" to refer to the notice. While petitioner refers to the statement as an "interpretive rule," the distinction between the two terms is immaterial in this context. *See United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) (noting that "interpretations contained in policy statements . . . are beyond the *Chevron* pale") (internal quotation marks omitted). *See* pages 16-17 *infra* (discussing various deference standards).

well as the conversion of leftover trimmings into ground beef products. *See* 64 Fed. Reg. 2804. In those situations, "[p]athogens may be introduced below the surface of these products as a result of the processes by which they are made." *Id.* The Agency thus stated that it views contaminated intact cuts in the same manner as non-intact cuts—that is, it regards them as "adulterated"—unless they "are to be distributed for consumption as intact cuts." *Id.*[4]

B. The Proceedings Below.

These consolidated cases were filed by, or on behalf of, persons who contracted E. coli O157:H7 food poisoning in July 2000, after eating at a Sizzler Restaurant in Milwaukee, Wisconsin. A three-year old girl, Brianna Kriefall, died as a result of the E. coli poisoning.[5]

The suits named several defendants, including respondent Sizzler and petitioner Excel. The claims against petitioner, all grounded in state law, included claims based on negligence, negligence per se for violating provisions of state law, and strict liability. *See, e.g.*, Kriefall Plaintiffs' Second Amended Complaint ¶¶ 100-139; Lesak Plaintiffs' First Amended Complaint ¶¶ 4.1-6.9. Plaintiffs also asserted various warranty claims against petitioner, including breach of express warranty, contending that they were third party

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[4] There are open questions about the extent to which the USDA has implemented the policy statement. *See* 65 Fed. Reg. 6881, 6886 (Feb. 11, 2000) (noting that the Agency "delayed implementation of the policy discussed in the January 19, 1999 policy statement because it was waiting for the results of the risk assessment for E. coli O157:H7 in ground beef and needed time to consider comments received concerning the policy"). Nonetheless, for purposes of this brief, we will assume that the policy has been implemented.

[5] Petitioner sought to remove the cases to federal court, basing its argument on the pervasiveness of the federal regulatory program. The federal district court rejected this argument and remanded the cases to state court.

beneficiaries of those warranties. *See, e.g.*, Kriefall Plaintiffs' Second Amended Complaint ¶¶ 140-181; Lesak Plaintiffs' First Amended Complaint ¶¶ 7.1-7.4.

Respondent Sizzler filed a cross-claim against petitioner. The cross-claim alleged that, through a contractual "continuing guarantee," petitioner had agreed to provide Sizzler with beef products that met all federal and state standards. *See, e.g.*, Sizzler USA Franchise, Inc. Cross-Claim ¶¶ 10, 12, 14, 16. In addition, it alleged that petitioner had undertaken obligations, and made affirmative representations, with respect to the quality and safety of its products. *See, e.g.*, *id.* ¶¶ 13-17. The cross-claim asserted causes of action based on breach of contract, fraud in the inducement, and breach of express and implied warranties. *See id.* ¶¶ 51-86.

The circuit court granted summary judgment for petitioner, finding that federal law preempted the state-law claims. Noting that, according to the 1999 USDA policy statement, "'intact products that are to be distributed for consumption as intact cuts are not deemed adulterated,'" Pet. App. 49a (quoting 64 Fed. Reg. 2804), the court held that the state-law tort claims fell within the terms of the Act's express preemption clause, 21 U.S.C. § 678, which bars States from imposing "[r]equirements . . . with respect to premises, facilities and operations of any establishment . . . which are in addition to, or different than those made under this chapter . . . . " *Id.* (The preemption clause is set forth in full at Pet. App. 60a.) Although respondents had argued, as a matter of fact, that the products sold by petitioner were *not* "intact products that are to be distributed for consumption as intact cuts," the circuit court did not resolve, or even acknowledge, this factual dispute. Nor did the court discuss whether state-law tort suits imposed "requirements" within the meaning of the express preemption clause, or, if they did so, whether those "requirements" were properly considered to be "with respect to premises, facilities and operations" of an inspected

establishment. Rather, after reviewing the extent of federal regulation under the Act, the court simply concluded that "[t]he federal regulatory scheme is so long-standing and so comprehensive that . . . it preempts any state laws to the contrary." Pet. App. 50a.

The circuit court also granted summary judgment on the contractual and warranty claims. *See* Pet. App. 50a. As to plaintiffs' claims, the court declared that "warranty claims require privity, and the plaintiffs here were not in privity with [petitioner] in the 2000 sale." *Id.* More generally, the court found that a "merger clause" in a January 2000 agreement between petitioner and Sysco Services—which had purchased the contaminated meat in question from petitioner and then resold it—precluded reliance on the terms of earlier agreements containing warranties and representations made by petitioner. It thus held that, while plaintiffs might pursue their claims against other defendants, "they may not sue Excel." *Id.*

The court of appeals reversed. With respect to the express preemption issue, the court concluded that the USDA policy statement cited by the circuit court was not dispositive in this case for two independent reasons. First, it observed that the policy statement regarded as not adulterated only intact cuts "that are to be distributed for consumption as intact cuts," and that the HACCP plan adopted by petitioner expressly indicated that "intact cuts of beef [at petitioner's plant] were 'intended to be sold raw . . . for further processing at retail.'" Pet. App. 18a (quoting the HACCP plan). Second, it concluded that the USDA policy statement—which necessarily viewed some intact cuts contaminated with E. coli O157:H7 as not potentially "injurious to health"—was inconsistent with the language and purpose of the Act. *See* Pet. App. 19a; 21 U.S.C. § 601(m)(1), (4). The court thus held that "the statutory definition controls." *Id.*

The court of appeals also found that the state-law claims were compatible with the scheme of federal regulation as a whole. In so doing, the court of appeals emphasized the numerous steps that the USDA had taken to eliminate E. coli O157:H7 in meat processing facilities. The court observed that, as the USDA had shifted its focus from reliance on its own monitoring activities to reliance on HACCP plans implemented and enforced by the establishments themselves, *see* Pet. App. 21a, it had taken a rigorous stance with respect to fecal contamination, *see* Pet. App. 24a-26a, imposing a policy of "zero tolerance." Pet. App. 26a. Likewise, it noted declarations by the USDA that the Agency "'considers an acceptable reduction for E. coli O157:H7 to be a reduction to an undetectable level.'" *Id.* (quoting 67 Fed. Reg. 62,329). Given the USDA objective of eliminating E. coli O157:H7 contamination during the slaughtering process, the court of appeals reasoned that state-law suits based on illnesses caused by contaminated meat would reinforce, not contradict, the provisions of federal law.[6]

The Supreme Court of Wisconsin denied a petition for review. Pet. App. 44a.

ARGUMENT

This case does not warrant further review. To begin with, the state court judgment is not final. *See* 28 U.S.C. § 1257(a). Although petitioner argues that this Court may exercise

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[6] The court pointed out that the USDA itself had recognized "the significant limitations of the 'organoleptic examination by inspectors,'" Pet. App. 32a (quoting 61 Fed. Reg. 38,838), especially with respect to organisms like E. coli O157:H7. It observed that "seven-foot-long carcasses arrive at the fabrication area after whizzing by the Service inspection station at the rate of one side every six seconds." *Id.* And, while those carcasses are later split into "some 8,000 intact cuts of beef weighing approximately two to four or three to five pounds each," *id.*, "[f]ederal inspectors do not inspect each one of these smaller cuts of beef." *Id.*

jurisdiction because reversal of the judgment would be "'preclusive of any further litigation,'" Pet. 16 n.4 (quoting *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 482 (1975)), that argument is clearly incorrect. For one thing, the Wisconsin Court of Appeals found that petitioner—as a distributor of meat cuts that may receive "further processing," rather than cuts sold only for "consumption as intact cuts" (64 Fed. Reg. 2804)—would not benefit from the very USDA policy statement that it seeks to rely on, regardless of whether the policy statement received judicial deference or not. Furthermore, the issue of how much (if any) deference is due to the Agency policy statement regarding E. coli O157:H7—the sole issue raised by the Question Presented (Pet. i)—is just one of many issues that would have to be resolved in petitioner's favor before it would be entitled to termination of the lawsuits against it. The court of appeals, in the opinion below, expressly left those other issues open.

Even leaving prematurity aside, the decision is correct and of little general importance. Because the policy statement issued by the USDA is concededly not entitled to *Chevron* deference, *see Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the only question is whether it is entitled to *Skidmore* deference, *see Skidmore v. Swift & Co.*, 323 U.S. 134 (1944): that is, in specific terms, whether the Agency has persuasively established that it is acceptable to regard certain cuts of meat contaminated with E. coli O157:H7 as not potentially "injurious to health." *See United States v. Mead Corp.*, 533 U.S. 218, 235 (2001) (deference given to agency judgments under *Skidmore* in accordance with their "power to persuade"). Looking to the language and purpose of the statute, and to the overall USDA objective of eliminating E. coli O157:H7 from meat processing facilities, the court of appeals reasonably concluded that a policy of regarding some E. coli O157:H7 contaminated meat as harmless was not persuasive enough to warrant deference. Furthermore, the decision below established no ground-

breaking principle of law, but merely determined that one particular USDA policy statement, applying to a single type of bacterium in a single situation, would not be regarded as definitive in a state-law tort suit. Nothing in that decision calls for review by this Court.

I. THE JUDGMENT BELOW IS NOT FINAL.

The express terms of 28 U.S.C. § 1257(a) establish that this Court has jurisdiction to review only "final judgments or decrees" from state courts. *See Jefferson v. City of Tarrant*, 522 U.S. 75 (1997). Although this requirement does not mean that state-court proceedings must always be terminated in their entirety, *see Cox Broadcasting*, 420 U.S. at 477, the Court has agreed to review issues in the midst of ongoing state cases in only a few narrow categories of cases. Petitioner tries to fit within one of those categories here, arguing in two-step fashion, *first*, that proper deference to the USDA policy statement would mean that "the state-law cause of action against Excel would be preempted," Pet. 16 n.4, and, *second*, that, as a result, "'reversal of the state court on the federal issue would be preclusive of any further litigation.'" *Id.* (quoting *Cox Broadcasting*, 420 U.S. at 482-83).[7] But this chain of reasoning is demonstrably wrong. For

[7] This Court in *Cox* noted that it had reviewed judgments from state courts, *inter alia*, in "situations where the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where *reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action* rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come. In these circumstances, if a refusal immediately to review the state court decision might seriously erode federal policy, the Court has entertained and decided the federal issue, which itself has been finally determined by the state courts for purposes of the state litigation." 420 U.S. at 482-83 (emphasis added).

a number of reasons, "a reversal . . . on the federal issue"—*i.e.*, the extent of deference owed to the USDA policy statement—would not come close to being "preclusive of any further litigation" against petitioner.

A. The first problem faced by petitioner is that a reversal, rather than precluding all litigation against it, would not help it at all. The reason is simple: petitioner has not established that its product falls within the narrow category of meat products that may be deemed not adulterated, even though they are contaminated with E. coli O157:H7. Thus, while petitioner describes the USDA E. coli O157:H7 policy statement as though it permitted the sale of all intact cuts, *see* Pet. 2, 10, 20, that characterization is notably incomplete: in fact, the policy statement makes an important distinction *within* the category of intact cuts, explicitly treating contaminated intact cuts as "adulterated" if they may be subject to further processing. *See* 64 Fed. Reg. 2804. In addressing petitioner's efforts to rely on the USDA policy statement, the court of appeals specifically recognized the difference between various categories of intact cuts, observing that the possible use of a particular meat product was necessarily of critical significance in determining whether it was "adulterated" under that standard. *See* Pet. App. 18a. Then, referring to petitioner's HACCP plan, the court pointedly observed that "its intact cuts of beef were 'intended to be sold raw . . . *for further processing at retail*.'" Pet. App. 18a (emphasis added).

Petitioner candidly acknowledges this defect in its position, conceding that the court of appeals "intimated that the meat involved in this case therefore should be classified as non-intact." Pet. 14 n.3. It then goes on to argue, however, that the court of appeals was mistaken, claiming that "the meat products produced by Excel that ended up at the E&B Sizzler restaurant were intact cuts of sirloin." *Id.* But that assertion, even if correct as stated, is beside the point: the issue is not

whether the products received at Sizzler "were intact cuts of sirloin," but whether the products were necessarily *to be consumed as intact cuts* without additional processing. On that question, as respondents argued below, a proper evidentiary record would show full awareness by petitioner that the type of cuts at issue here (so-called "tri-tips," weighing from three to five pounds) would routinely be subject to further processing at other facilities or at retail establishments (like Sizzler), including mechanical tenderizing processes that can cause E. coli O157:H7 to penetrate to the interior of the meat. *See*, *e.g.*, C.A. Brief of Lesak Plaintiffs-Appellants 23-32. It thus was entirely appropriate for the court of appeals to decide that, according to the terms of its own HACCP plan, petitioner was in no position to use the USDA policy statement to avoid liability.

In any event, with respect to petitioner's factual contentions, it seems obvious that this Court is not the forum in which to resolve whether petitioner did, or did not, distribute meat that might receive further processing. The case is before the Court on reversal of a summary judgment, and these sorts of factual questions have yet to receive a full airing. Whatever the ultimate outcome, it is clear under Wisconsin law that "[d]oubts as to the existence of a genuine issue of material fact should be resolved against the party moving for summary judgment." *Grams v. Boss*, 294 N.W.2d 473, 477 (Wisc. 1980); *see also Lambrecht v. Estate of Kaczmarczyk*, 623 N.W.2d 751, 759 (Wisc. 2001) (same). Under that standard, the court of appeals rightly treated petitioner as a distributor of intact cuts "for further processing at retail," not as a distributor of cuts "for consumption as intact cuts." As such, petitioner would not be entitled to judgment in its favor, regardless of the deference given to the USDA policy statement.

B. A reversal would not preclude further litigation against petitioner for other reasons as well. Even if petitioner were to

prevail on the "deference" issue that it raises in the Question Presented, and even if petitioner would actually benefit from that deference, it still would have taken only the first of several required steps towards obtaining dismissal of respondents' claims. As the court of appeals made clear below, several other important issues remain open, if necessary, in further proceedings.

The first of those outstanding issues is whether the state-law claims at issue would constitute "requirements" within the meaning of the Act's express preemption clause. *See* 21 U.S.C. § 678 ("[r]equirements within the scope of this chapter with respect to premises, facilities and operations of any [inspected] establishment . . . which are in addition to, or different than those made under this chapter may not be imposed by any State . . . .") Although this Court has indicated that state-law claims may constitute "requirements" under the language of a particular preemption provision, *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality opinion); *id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part), it is hardly self-evident that they always do so, or that they would do so here. Indeed, the language of the Federal Meat Inspection Act preemption clause, read in context, would appear more naturally to refer to formal state administrative requirements, rather than to common law remedial actions arising out of injuries suffered as a result of contaminated products. Moreover, it is noteworthy that the Act contains no right of action for consumers killed or made ill by contaminated meat products, even though Congress was surely aware that, notwithstanding the USDA inspection process, hundreds of people are exposed each year to unsafe meat. To insist upon preemption of all state claims arising out of "approved" meat products thus would require an assumption that Congress meant to bar States from affording relief to their citizens in an area (public health) that is of traditional state concern—an assumption that is contrary to the usual understanding of what

Congress intends. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress'") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("common-law claims . . . necessarily perform an important remedial role in compensating accident victims"). The court of appeals, while noting the difficulties raised by this issue, expressly declared that it was not resolving it. *See* Pet. App. 6a n.3.

There are also open questions regarding whether the various claims in this case, assuming that they impose "requirements" at all, would do so "with respect to premises, facilities and operations" of an inspected establishment and would be "in addition to, or different than" the relevant federal requirements. Again, the court of appeals expressly reserved decision on the proper application of that language. *See* Pet. App. 8a n.3. The term "with respect to" has no defined meaning in this context, and the phrase may reasonably be read to refer to specific targeted requirements, rather than to more general tort requirements (*e.g.*, negligence or strict liability) that happen to have an incidental effect on meat processing operations. *See generally California Div. of Labor Standards Enforcement v. Dillingham Constr. N.A., Inc.*, 519 U.S. 316 (1997). Moreover, as we discuss later, the USDA has established a policy of "zero tolerance" with respect to fecal contamination in inspected establishments, and it has further declared that E. coli O157:H7 should be reduced to "undetectable levels." *See* pages 20-21 *infra*. The claims here, which result from meat contaminated with E. coli O157:H7, are entirely consistent with—indeed, affirmatively reinforce—those objectives.

Finally, there are significant remaining questions about whether petitioner has undertaken voluntary contractual and warranty obligations that are enforceable without regard to any preemption defense. Given its disposition of the case, the court of appeals once again found no need to address those issues. *See* Pet. App. 36a n.8. But it is well-recognized that, preemption law notwithstanding, companies may properly be held accountable for failing to comply with contractual or other representations. *See American Airlines, Inc. v. Wolens*, 513 U.S. 219, 232-33 (1995); *Cipollone*, *supra*, 505 U.S. at 525-27 (plurality opinion). Although the Wisconsin circuit court held that respondents could not rely on petitioner's voluntary undertakings because of a lack of privity, and because of a merger clause in a subsequent contract, there are strong reasons to think that the court misread both the terms of the relevant contracts and Wisconsin law. *See* C.A. Brief of Defendant-Third Party Sizzler USA Franchise, Inc. 18-30. Hence, petitioner faces liability on those grounds, regardless of its success (or lack of it) in establishing preemption of other claims.

The final judgment requirement is "not one of those technicalities to be easily scorned." *Radio Station WOW, Inc. v. Johnson*, 326 U.S. 120, 124 (1945). Rather, "[i]t is an important factor in the smooth working of our federal system." *Id. See also Costarelli v. Massachusetts*, 421 U.S. 193, 196 (1975) (rule "prevent[s] our interference with state proceedings when the underlying dispute may be otherwise resolved"). As this Court has said: "The finality requirement of 28 U.S.C. § 1257 . . . serves several ends: (1) it avoids piecemeal review of state court decisions; (2) it avoids giving advisory opinions in cases where there may be no real 'case' or 'controversy' in the sense of Art. III; (3) it limits review of state court determinations of federal constitutional issues to leave at a minimum federal intrusion in state affairs." *North Dakota State Bd. of Pharmacy v. Snyder's Drug Stores, Inc.*,

414 U.S. 156, 159 (1973). Those principles are fully applicable here. The petition is premature.

II. THE PETITION DOES NOT, IN ANY EVENT, WARRANT REVIEW.

Quite apart from its procedural faults, the petition raises no issues meriting review by this Court. Although petitioner vigorously argues that the USDA E. coli O157:H7 policy statement is entitled to deference, and that the court of appeals impermissibly failed to give it "any weight," *see, e.g.*, Pet. i, 16, that narrow question—involving one out of thousands of federal rules and policy statements—is of no general importance. And, in any event, the court below was right to conclude that, in light of the governing statute and the regulatory scheme as a whole, there was no reason to accord deference to one questionable aspect of this particular USDA policy statement.

A. At the outset, we note that petitioner does not make any argument that the Wisconsin court was required to give *Chevron*-type deference to the USDA policy statement. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). This Court has held that the more substantial *Chevron* deference is generally reserved for rules adopted after notice-and-comment rulemaking. *See United States v. Mead Corp.*, 533 U.S. 218, 229-30 (2001). Although the Court has recognized a few additional situations in which *Chevron* deference is appropriate, *see id.* at 231, nothing in the actions of the USDA with respect to the E. coli O157:H7 policy statement—even assuming that it has actually been implemented, *see* note 4 *supra*—brings them within that limited class. Consequently, the court of appeals was under no obligation to defer to the Agency pursuant to the standards of that doctrine.

The policy here thus would be entitled to, at most, *Skidmore*-type deference. *See Skidmore v. Swift & Co.*, 323

U.S. 134 (1944); *see also Mead*, 533 U.S. at 234-35; *Christensen v. Harris County*, 529 U.S. 576, 587 (2000). As this Court has indicated, that kind of deference acknowledges that government agencies may develop levels of experience and knowledge in the course of administering federal statutes. *See Mead*, 533 U.S. at 234-35. This recognition does not mean, however, that courts must follow agency interpretations of federal law. Rather, under the standards of *Skidmore* deference, the agency view is to be given respect to the extent of, but only to the extent of, its "power to persuade." *See Mead*, 533 U.S. at 235; *Christensen*, 529 U.S. at 587.

Nothing in the decision below is contrary to these principles. All that the court of appeals did—and what, under *Skidmore*, it was fully entitled to do—was to determine that, insofar as the applicable USDA policy statement posited that certain intact cuts contaminated with E. coli O157:H7 were not potentially "injurious to health," it lacked the "power to persuade." The court noted that the relevant statutory language defined adulterated products in terms of whether poisonous substances or insanitary conditions "may render" meat products "injurious to health," *see, e.g.*, 21 U.S.C. § 601(m)(1), (4), and it further noted that the overriding purpose of the statute was to safeguard public health against the harm posed by contaminants like E. coli O157:H7. *See* Pet. App. 10a; *see also* 21 U.S.C. § 602 ("[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged"). Given the Act's language and purpose, and the USDA's own explanations regarding the severe dangers arising from E. coli O157:H7, the court below simply concluded that the presence of E. coli O157:H7 on meat products posed the kind of threat to public

health targeted by the statute, at least under the circumstances present here.[8]

This reasoning makes sense for several reasons. In the first place, there is no doubt that E. coli O157:H7 is a "poisonous or deleterious substance," *see* 21 U.S.C. § 601(m)(1), and that it may occur "under insanitary conditions." *See* 21 U.S.C. § 601(m)(4). Moreover, E. coli O157:H7 is indisputably capable of causing serious harm, even in small quantities. The USDA itself has stated: "Some pathogens, such as E. coli O157:H7 are so virulent that a small number of organisms can pose a significant hazard," 61 Fed. Reg. 38,835, concluding that "any amount of E. coli O157:H7 will adulterate a meat or poultry product." *Id.*; *see also* 65 Fed. Reg. 6883 ("E. coli O157:H7 is a particularly virulent pathogen").[9]

It is also clear that "[t]he public health risk presented by beef products contaminated with E. coli O157:H7 is not

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[8] We note that there might be grounds for claiming more than *Skidmore* deference to the views of the Secretary under 21 U.S.C. § 601 (m)(2), which defines one kind of adulterated product and explicitly leaves the question whether a substance makes a product "unfit for human food" up to the "judgment of the Secretary." *See id.* As the court of appeals pointed out, however, that language is absent from the other definitional provisions of Section 601(m). *See* Pet. App. 19a.

[9] Although petitioner compares E. coli O157:H7 to other forms of bacteria like Salmonella and trichinae spiralis, *see* Pet. 24, the question whether various pathogens may be injurious to health does not lend itself to a one-size-fits-all answer. For example, the USDA has declared that the threat posed by E. coli O157:H7 is greater than the threat posed by other bacteria that are harmful only in far larger quantities. *See, e.g.*, 61 Fed. Reg. 38,835 (noting that, in contrast to E. coli O157:H7, salmonella "must multiply to relatively large numbers to cause illness"). Thus, whether a particular product can safely be sold, despite the presence of bacteria, will necessarily depend on both the nature of the product and the particular bacterium at issue. The decision in this case involves only E. coli O157:H7.

limited . . . to raw ground beef products." 64 Fed. Reg. 2803. As the USDA policy statement recognizes, intact cuts commonly are subjected to further processing, which can cause the E. coli O157:H7 bacteria to penetrate below the surface of the meat. Thus, if meat contaminated with E. coli O157:H7 could ever sensibly be regarded as safe for distribution to consumers, it would have to be under circumstances where there was sufficient assurance, at the time of inspection, that the contaminated cuts would be consumed without further treatment. *See* 64 Fed. Reg. 2803 (noting importance of "adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed"). There is nothing even approaching that assurance here. To the contrary, as the court of appeals noted, it was generally understood that the intact products at petitioner's facility, like those at many other meat processing facilities, were likely to receive further processing. *See* Pet. App. 18a (discussing petitioner's HACCP plan). Indeed, an Excel official testified at his deposition that Excel plant employees (and, presumably, USDA inspectors) typically do not know the intended use of the carcasses presented for examination and approval. *See* C.A. Lesak Brief 30-31 (quoting Klingaman Aff., Ex. E., Goltry Dep. at 322-24). Under those circumstances, it is simply not possible to predict, with any reliable level of confidence, that a particular carcass or large cut of meat contaminated with E. coli O157:H7 would not be potentially "injurious to health."

Petitioner suggests, however, that the words "may render it injurious to health" should be given a narrow reading, in order to exclude highly speculative or remote risks arising from commonly-occurring bacteria. *See* Pet. 21, 24. But the risks here were not remote. The court of appeals had ample evidence—much of it contained in declarations by the USDA itself—from which to conclude that the dangers posed by E. coli O157:H7 were neither fanciful nor inconsequential, even with respect to intact cuts. Thus, while petitioner is doubtless

correct that some levels of risk may be too slight to fall within the statutory terms, the presence of E. coli O157:H7 gives rise to significantly more serious concerns.[10]

It is also important to recognize that, under the USDA regulatory approach, meat processors cannot simply assume that later handling will eradicate the risk posed by highly dangerous pathogens like E. coli O157:H7. Thus, while petitioner seeks to rely on the fact that "the bacteria are killed by ordinary cooking," Pet. 20, the Agency has emphasized the importance of eliminating potential hazards *before* harmful products are distributed to the public. *See* Pet. App. 27a (discussing USDA approach). The USDA thus has noted that the "first, and critical step" leading to foodborne illness is "the introduction of a pathogen into or onto the raw product," 61 Fed. Reg. 38,966, a step that only takes place as a result of improper slaughtering and processing. Although it is certainly true that "ordinary cooking" may reduce the chances of resulting illness, the USDA found no justification for processors to ignore the problem at its source, stating that "disease would not have occurred if the pathogen had not been present on the raw product in the first place." *Id.*

The objective of preventing E. coli O157:H7 contamination at the slaughterhouse is directly reflected in the USDA policies regarding meat processors' HACCP plans. The USDA has stated that "preventing and removing fecal contamination and associated bacteria are vital responsibili-

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[10] In *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), this Court indicated that similar language in a federal statute ("may be injurious to health") is properly construed to take account of potential harm even to unusually susceptible consumers. Noting that flour (the product there at issue) "may be consumed . . . by the old and the young, the well and the sick," *id.* at 411, the Court in *Lexington Mill* concluded that "if any flour, because of any added poisonous or other deleterious ingredient, *may possibly injure* the health of any of these, it shall come within the ban of the statute." *Id.* (emphasis added).

ties of slaughter establishments," 61 Fed. Reg. 38,837, which establishments—rather than the USDA—now bear the primary responsibility for meat safety. *See* page 3 *supra*. Importantly, given the suggestions by petitioner that harmful bacteria are an inevitable aspect of dealing with meat products, Pet. 21, 24, the Agency has made a point of saying that "such contamination is largely preventable." *Id.* Thus, the Agency has indicated that, in HACCP plans, it will require "a slaughter establishment's adherence to zero tolerance for fecal contamination." 61 Fed. Reg. 38,850. Taking a similarly stringent view with respect to E. coli O157:H7 itself, the Agency has said that it "considers an acceptable reduction for E. coli O157:H7 to be a reduction to an undetectable level." 67 Fed. Reg. 62,329.

In light of this broad statutory and regulatory background, therefore, the court of appeals was fully justified in concluding that meat contaminated with E. coli O157:H7 was, in a very real sense, potentially "injurious to health," within the meaning of 21 U.S.C. § 601(m). Not only does the USDA acknowledge the dangers posed by even a small amount of E. coli O157:H7, it further recognizes that meat processors cannot always depend on later handling to eliminate the danger. It follows, therefore, that the distribution of meat products contaminated with E. coli O157:H7—whether they are "intact cuts" or not—can lead to just the sort of harm to unsuspecting consumers that occurred here. To the extent that parts of the USDA "adulteration" policy statement can be taken to indicate otherwise, it lacks persuasive force and need not be given judicial deference.

B. The decision below is also of limited importance. The Wisconsin Court of Appeals announced no novel principles regarding whether, and when, to give deference to federal administrative agencies. Rather, it simply declined to apply one aspect of one policy statement addressing one particular hazardous contaminant, solely for the purpose of adjudicating

certain state-law tort claims. While the decision declines to follow petitioner's view of the USDA policy statement with respect to those particular claims, nothing in the decision bars the Agency—which, after all, was not a party to these proceedings—from deciding for itself how to carry out its discretionary enforcement duties. Nor does it take any position with regard to meat products contaminated with pathogens other than E. coli O157:H7.

Although petitioner argues that the decision below will create widespread uncertainty about the obligations of meat processing facilities, Pet. 22-26, this concern is overstated. As noted, the USDA already requires facilities to adopt stringent standards in order to prevent fecal contamination, seeking to eradicate the incidence of E. coli O157:H7. *See* pages 2-4, 21 *supra*. Insofar as those objectives are in question, therefore, the state court view of E. coli O157:H7 as a potentially dangerous substance, even on most intact cuts, poses no obstacle to the federal program. If anything, the possibility of state liability actions provides a complementary incentive to rid processing facilities of the threat posed by fecal contamination.

To be sure, the ruling below does raise the prospect that slaughterhouses and processors may face liability for injuries or deaths caused by the sale of contaminated meat, even if that meat has managed to pass through the federal inspection process. But, as the court of appeals noted, petitioner cannot expect that federal inspection will result in detection and disapproval of all contaminated meat, given that inspectors (relatively few in number, to begin with) are exposed to 350-pound carcasses for approximately six seconds apiece. *See* Pet. App. 32a. Indeed, petitioner has workers known as "defect trimmers" that are assigned to remove fecal contamination *after* the carcasses have received "approval" at the slaughtering stage. Furthermore, it is significant that the USDA conducts random testing and evaluation at *retail*

establishments, necessarily reflecting its own understanding that pre-distribution inspection is not a foolproof system.[11] It is thus entirely appropriate to preserve the opportunity for injured consumers to obtain relief from processors that sell contaminated meat products.

Petitioner also asserts that the decision below raises the prospect of disuniformity, contrary to congressional intent. Pet. 15, 22, 26. But this argument, familiar to most preemption cases, is largely out of place here. Unlike areas like labeling and packaging—where the need for uniformity is typically at its highest (*see, e.g., Jones v. Rath Packing Co.*, 430 U.S. 519 (1977))—the operations of each processing facility are conducted according to its own HACCP plan, which naturally will vary according to the particular needs and concerns of the individual facility. *See* Pet. App. 31a-32a. At the same time, of course, all HACCP plans share the common goal of eliminating fecal contamination and E. coli O157:H7. Again, in that regard, the decision below helps to promote uniformity, not to undermine it.

C. Finally, petitioner says that the decision below is in conflict with *Boulahanis v. Prevo's Family Market, Inc.*, 583 N.W.2d 509 (Mich. 1998), *cert. denied*, 530 U.S. 1203 (2000), and several decades-old cases from federal courts of appeals. The *Boulahanis* decision, however, involved a sale of meat prior to the time that the USDA regarded E. coli O157:H7 as a threat to public health. Thus, unlike the present case, there was no regulatory history of USDA efforts to eradicate E. coli O157:H7 in processing plants, reinforced by

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[11] The lack of absolute certainty with respect to inspected meat products is illustrated by the fact that, prior to 1994, the USDA did not specifically include E. coli O157:H7 in its list of adulterants, in spite of its highly virulent nature. During that earlier period, therefore, USDA inspectors would have "approved" even ground beef contaminated with E. coli O157:H7, although the Agency now acknowledges that contaminated ground beef plainly may be "injurious to health."

Agency recognition that it was necessary to stop E. coli O157:H7 at the source rather than to depend upon later handling to neutralize already-present contamination. Without that background, the Michigan court had no sufficient reason to question the implicit USDA determination—which proved mistaken, of course, and has since been abandoned—that the sale of meat (there, ground meat) contaminated with E. coli O157:H7 was not potentially "injurious to health." Its decision, therefore, does not conflict with the decision below, which takes account of a very different regulatory record.

There is also no conflict with the cited federal cases. *See Grocery Manufacturers of Am., Inc. v. Gerace*, 755 F.2d 993 (2d Cir. 1985); *National Pork Producers Council v. Bergland*, 631 F.2d 1353 (8th Cir. 1980); *Public Citizen v. Foreman*, 631 F.2d 969 (D.C. Cir. 1980). In the first place, each of the regulations at issue in those cases was promulgated after a far more formal and extensive process. *See Gerace*, 755 F.2d at 1001 (citing *Federation of Homemakers v. Schmidt*, 539 F.2d 740 (D.C. Cir. 1976), which had upheld an underlying FDA rule promulgated after notice and comment, *see id.* at 742); *Bergland*, 631 F.2d at 1357; *Foreman*, 631 F.2d at 973. Those cases thus raised questions of *Chevron*-type deference, *see Mead*, 533 U.S. at 229-30, a degree of deference that petitioner does not, and could not, ask for here. Moreover, not surprisingly, none of those federal courts held, or had any reason to hold, that USDA policy statements (or interpretive rules, *see* note 3 *supra*) must be treated as authoritative even if they lack the "power to persuade," and they certainly did not indicate that deference must be given to pronouncements that are inconsistent with either the import of the governing statute or other pronouncements of the USDA itself. The claimed conflict is thus entirely imaginary.

In short, the petition is too little, too soon. Further review is not warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

RUSSELL A. KLINGAMAN
HINSHAW & CULBERTSON
100 E. Wisconsin Avenue
Milwaukee, WI 53202
(414) 276-6464

WILLIAM D. MARLER
DENIS W. STEARNS
MARLER CLARK, LLP, PS
4301 Bank of America Tower
701 Fifth Avenue
Seattle, WA 98104
(206) 346-1888

WILLIAM M. CANNON
EDWARD E. ROBINSON
CANNON & DUNPHY, S.C.
595 North Barker Road
Brookfield, WI 53008
(262) 787-2700

H. BARTOW FARR, III
FARR & TARANTO
1220 19th Street, N.W.
Suite 800
Washington, D.C. 20036
(202) 775-0184

FREDERIC L. GORDON
Counsel of Record
RHONDA J. HOLMES
GORDON & HOLMES
1230 Columbia Street
Suite 700
San Diego, CA 92101
(619) 696-0444

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No. 03-862

In the Supreme Court of the United States

EXCEL CORPORATION,

Petitioner,

v.

ESTATE OF BRIANNA L. KRIEFALL, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

REPLY BRIEF FOR PETITIONER

RALPH A. WEBER
AMELIA L. MCCARTHY
SHAWN K. STEVENS
Gass Weber Mullins LLC
309 North Water Street
Milwaukee, WI 53202
(414) 223-3300

ANDREW J. PINCUS
Counsel of Record
RICHARD B. KATSKEE
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Petitioner

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REPLY BRIEF FOR PETITIONER

The decision below displaces the considered, long-established views of the expert federal agency that Congress authorized to interpret and implement the Federal Meat Inspection Act (FMIA), eliminates the uniformity mandated by Congress, and opens the door to multiple conflicting state standards that would make it virtually impossible to distribute meat without the risk of substantial criminal and civil penalties. Respondents nonetheless assert that the decision below is unworthy of this Court's attention. In part they claim that the consequences of the ruling will be trivial, and in part they contend that uniform regulation of meat safety is neither necessary nor desirable.

The *amici curiae* supporting the petition have conclusively refuted the former argument and Congress has by statute foreclosed the latter. But the federal government obviously is the most knowledgeable authority on the flaws in the decision below and its adverse effect on the Secretary of Agriculture's administration of the FMIA. The Court therefore may wish to invite the Solicitor General to file an *amicus* brief in this case expressing the views of the United States.

Alternatively, because the court of appeals' ruling is plainly inconsistent with this Court's recent decision in *Alaska Department of Environmental Conservation* v. *EPA*, 124 S. Ct. 983 (2004), the Court may wish to consider granting the petition, vacating the judgment below, and remanding the case for reconsideration in light of that intervening authority.

1. Apparently desperate to insulate the court of appeals' decision from this Court's scrutiny, respondents expend considerable energy arguing that this Court lacks jurisdiction because the decision below supposedly is not final under *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469 (1975). They do not dispute that the federal issue has been determined finally by the

Wisconsin court; their entire argument is that the case does not satisfy *Cox*'s statement that reversal of the state court on the federal issue should be preclusive of further litigation. Respondents are plainly wrong.

To begin with, their argument rests on a mischaracterization of the issue before this Court; they proceed as if we had sought review only of the narrow issue whether deference should be accorded to the Secretary's policy. In fact, the question presented to this Court is whether that policy should have been accorded deference *and* upheld in the circumstances of this case. *See* Pet. i. Thus, all of the alleged factual and legal issues raised by respondents are before this Court. If the Court resolves them, which it has the power to do, there will be no further litigation against petitioner on respondents' tort claims.

Moreover, respondents' contentions are baseless. For example, they imply (Opp. 11-12) that the court of appeals found that the meat at issue in this case was not "intact" within the meaning of the Secretary's policy because petitioner's HAACP plan "recognized that its intact cuts of beef were 'intended to be sold raw . . . for further processing at retail.'" Pet. App. 18a (omission in original). But the plan actually stated that meat from petitioner's plant was "intended to be sold raw (fresh or frozen) as packaged *or* for further processing at retail or export." Ct. App. Rec. 77 (emphasis added). The court of appeals accepted the trial court's determination that the meat here was *packaged* (*see* Pet. App. 11a, 17a (meat consisted of wrapped intact cuts)), which meant that it was *not* subject to further processing. Moreover, USDA regulations define "further processing" to mean additional preparation "in an official establishment" — such as a federally-inspected smoking or canning facility. 9 C.F.R. § 301.2. Because respondent Sizzler is not an "official establishment" under the FMIA, it could not as a matter of law subject meat to "further processing." Indeed, USDA has specifically acknowledged

that Excel meat of the sort at issue here qualifies as intact and unadulterated even if it bears *E. coli*. *See* Pet. App. 61a.

Respondents also try to argue (Opp. 13-14) that the FMIA's preemption provision might not apply either because the particular requirements imposed by state law here might not conflict with the federal standards or because state rules formulated in tort cases might be exempt from preemption. But respondents cannot obscure the fundamental fact that they seek to impose liability for an action (allegedly distributing intact meat bearing *E. coli*) that is authorized by federal law. While tort liability for conduct that *violates* federal law is entirely consistent with the statutory scheme, tort liability for *permissible* conduct plainly constitutes additional "[r]equirements * * * with respect to premises, facilities and operations" of federally-inspected establishments (21 U.S.C. § 678), because the threat of such liability will force meat processors such as petitioner to change the USDA-mandated and USDA-approved procedures at their plants across the country in order to comply with the standards imposed by the Wisconsin court (*see Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992); *id.* at 548-49 (Scalia, J., concurring in the judgment in part and dissenting in part)). Indeed, the court below acknowledged as much (*see* Pet. App. 30a), and it attempted to avoid the express preemption provision by replacing the Secretary's definition of "adulterated" with its own interpretation.[1]

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[1] Respondents cite *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), but state tort liability survived federal preemption there only because the state "requirements" were not "in addition to" federal ones; they merely afforded remedies to parties injured by violations of federal law whose losses would otherwise have remained uncompensated. *Id.* at 486-87. Here, there is no alleged violation of federal law because federal law plainly authorizes distribution of "unadulterated" meat that the court of appeals' decision expressly forbids.

Respondents imply that the Wisconsin court's decision not to address all of these issues somehow deprives this Court of jurisdiction (even though anything the lower court might have said with respect to these matters would have been unnecessary to its holding). That is simply wrong. In *Southland Corp.* v. *Keating*, 465 U.S. 1 (1984), the question was whether a California law regarding the arbitrability of certain disputes was preempted by the Federal Arbitration Act (FAA). The California Supreme Court did not address the contention that the FAA applied only to disputes that fell within the jurisdiction of the federal courts (645 P.2d at 1201), holding instead that the FAA did not preclude the State from barring waiver of judicial remedies. This Court did not conclude — as respondents urge here — that the failure to address that alternative ground for resolving the case foreclosed review. Instead, it held that jurisdiction was available under *Cox*. 465 U.S. at 6-7.

Finally, respondents assert that jurisdiction is precluded by the court of appeals' failure to address their contention that respondent Sizzler's state-law warranty claims would survive in the event the tort claims are preempted. Although we believe that the warranty claims are also preempted, whether those entirely separate causes of action may be maintained is irrelevant under *Cox*. In *Fort Wayne Books, Inc.* v. *Indiana*, 489 U.S. 46 (1989), this Court held that it had jurisdiction to consider a constitutional challenge to indictment for violations of Indiana's RICO statute despite the fact that the petitioner did not also challenge his prosecution for the predicate offenses. Because dismissal of the RICO counts "would bar further prosecution on [those] counts," the Court held that the case "clearly satisfie[d]" *Cox* — even though the predicate state-law counts remained pending against the petitioner. *Id.* at 55.

Respondents' attempts to deflect the Court's attention from the merits of the petition are thus unavailing: the Court has the power to resolve the important legal issues presented in this

case. Indeed, if respondents' interpretations of this Court's precedents were correct, then reconsideration of those precedents would be appropriate. Preemption issues arise very frequently in state-court proceedings — as defenses to tort claims or government action. If this Court's jurisdiction could be defeated by the mere fact that the lower court did not address possible alternative bases for its ruling, then a party could effectively foreclose review by raising alternative appellate arguments (meritorious or otherwise) sufficient to ensure that the state court would decline to decide — or would merely overlook — at least one of them. That would mean defendants could almost never obtain review by this Court of unfavorable state-court decisions (because remanded cases would fall within the more than ninety-five percent of cases settled before trial), while plaintiffs would be able to seek review (because a state-court decision upholding a preemption defense would necessarily address all of the alternative arguments advanced against preemption). As a theory of appellate jurisdiction, that unbalanced approach makes no sense.

2. Respondents devote most of their remaining effort to defending the *result* reached by the court of appeals, but they expend no effort whatsoever defending the court's *reasoning*. Their arguments serve principally to confirm the need for intervention by this Court.

Respondents assert that the lower court decided that the Secretary's construction "lacked the 'power to persuade.'" Opp. 17. But that is not what the court did; it held that the Secretary had no role whatever in defining "adulterated": "[n]one of the definitions of 'adulterated' in the Act makes a distinction between intact or non-intact meat," and therefore USDA "was powerless to add that distinction to Congress's definition." Pet. App. 19a. The court ignored the Secretary's policy and gave the broad terms of the statute a rigid interpretation that requires application of the "adulterated" label

to meat bearing virtually any substance that might possibly be harmful. *See* Pet. 13-14, 16-17; Pet. App. 13a-14a.[2]

Moreover, respondents' invented rationale is no more persuasive than the court of appeals' actual reasoning. They make three basic points. First, they simply disagree with the Secretary's judgment regarding the risks of *E. coli* O157:H7 on intact meat. Undertaking their own analysis, they conclude that "the risks here were not remote" and the court of appeals "had ample evidence" of those risks. Opp. 19. As the meat-industry *amici* explain (AMI Br. 17-19), however, the Secretary's judgment rests on detailed scientific analysis, including assessment of potential costs and benefits, by recognized experts of FSIS, the National Advisory Committee on Microbiological Criteria for Foods, the CDC, the National Academy of Sciences, USDA's Agricultural Research Service, and the National Institute of Allergy and Infectious Disease. *See also* Pet. 10. Respondents offer no reason why their armchair analysis is more persuasive.

Second, respondents try to create the impression that some of the Secretary's pronouncements support their position. Certainly the Secretary has set as a goal the elimination of all *E. coli* O157:H7, but the adoption of that target for meat processing facilities' inspection plans (*see* Pet. 6-7) does not mean that the Secretary has concluded that failure to achieve it should subject meat processors to criminal and civil liability for the shipment of adulterated meat. To the contrary, the Secretary has explicitly determined that imposing that liability

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[2] Thus, respondents' assertion (Opp. 18 n.9) that the decision below would not affect other naturally-occurring pathogens simply is not true of the decision that the court of appeals wrote; it applies only to the very different analysis respondents use to defend the result below.

is *not* appropriate for intact meat.[3] Respondents' selective quotations from USDA cannot obscure that basic fact.

Third, respondents' argument rests on misunderstandings about the inspection process. For example, they assert (Opp. 13) that Congress did not mean to preempt tort claims arising out of "approved" but "contaminated" meat. But we do not contend that USDA approval is the relevant standard; if meat is "adulterated" within the meaning of the statute, the processor is subject to liability — even if the meat was inspected and approved by the federal inspectors located at the plant. In addition, respondents' claim (Opp. 19) that federal inspectors and plant employees may not know the intended use of every carcass at the time of its inspection is beside the point. The FMIA requires federal inspectors to approve not only the carcasses, but also each meat product through the entire process, up until the time that it is sealed in a package and labeled for shipment and sale (21 U.S.C. § 607).

Not surprisingly, respondents fail to mention this Court's recent decision in *Alaska Department of Environmental Conservation v. EPA*. There, the Court adopted EPA's construction of the Clean Air Act even though not embodied in a formal rule, stating that "[c]ogent 'administrative interpretations . . . not the products of formal rulemaking . . . nevertheless warrant respect.'" 124 S. Ct. at 1001 (brackets and citation omitted). Significantly, the Clean Air Act's numerous

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[3] USDA first announced the goal of reducing the presence of *E. coli* in meat to "an undetectable level" in 2002, more than two years after the plaintiffs in this case were injured. 67 Fed. Reg. 62,325, 62,329 (Oct. 7, 2002). Respondents' attempt to equate that announcement with USDA's pre-existing "zero tolerance" standard for visible fecal material (Opp. 14, 21) is belied by the Secretary's recognition, in setting the standard, that elimination of visible fecal material does not guarantee meat to be bacteria-free. *See* Pet. 10-11 n.2.

assignments of specific rulemaking responsibilities to EPA did not include the issue before the Court, yet the Court — unlike the court below — did not find that the absence of specific authority obligated it to ignore completely the agency's interpretation of the statute. *See also id.* ("well-reasoned views of an expert administrator rest on a body of experience and informed judgment to which courts and litigants may properly resort for guidance") (quotation marks and citations omitted).

Given the close similarities between the two cases, this Court may wish to consider granting the petition, vacating the judgment below, and remanding the case for reconsideration in light of the intervening decision in *Alaska Department of Environmental Conservation.*

3. The practical consequences of the decision below for the meat industry are severe. The Wisconsin court blithely cast aside an important federal standard in an area in which uniform national regulation is critical. As the meat-industry *amici* explain, the court of appeals' declaration that the Secretary lacks authority to interpret the FMIA's key terms will erode the national rules that Congress and USDA have developed over the past century to bring predictability, stability, and uniformity to the meat processing industry on the one hand (AMI Br. 11-15), and to ensure stable supplies of wholesome, affordable meat for consumers on the other (*id.* at 15-17).

Respondents' principal arguments are that the effects on uniformity will not be that great and that uniformity is not really necessary in any event. Both are demonstrably false.

Because the definition of "adulterated" is the cornerstone of the federal regulatory program for ensuring meat safety, the court of appeals' displacement of the Secretary's authority to interpret that term undermines her ability to identify and prioritize potential health threats to consumers and to direct scarce resources to meet the most pressing ones (especially

important when urgent threats such as Mad Cow Disease impose competing demands on those resources). *See* Pet. 24; AMI Br. 15. In commenting (Opp. 22) that the court below lacks formal authority to order the Secretary to alter how she implements the FMIA, respondents ignore the central issue that, by authorizing additional and potentially conflicting standards, backed by criminal and civil sanctions, the decision seriously undercuts the Secretary's ability to orchestrate a coherent regulatory program that best serves the Act's objectives.

And although respondents may not value uniformity in the regulation of meat (Opp. 23), Congress plainly does (*see* 21 U.S.C. §§ 602, 678). In holding that the Secretary's interpretation of "adulterated" may not be accorded any judicial respect, the decision of the court below stands as a blueprint for other state courts, legislators, and regulators to impose on meat processors their own idiosyncratic views — and not just with respect to meat safety. As the Product Liability Advisory Council explains in its *amicus* brief, the decision implicates the authority of federal agencies to administer critically important federal statutes dealing with, among other things, safety standards for food, drugs, medical devices, cosmetics, motor vehicles, and a broad array of other consumer products. *See* PLAC Br. 7-12; *see also* AMI Br. 13.

If the Court has any doubts about either the dramatic consequences to the meat processing industry or the substantial threat to USDA oversight of meat safety, it may wish to invite the Solicitor General to file an *amicus* brief expressing the views of the United States — especially given USDA's clear reaffirmation of its policy following the events at issue in this case. *See* Pet. App. 61a.

4. Respondents' attempts to distinguish the decisions that conflict with that of the court below simply confirm the existence of a conflict that this Court should resolve.

They point out that *Boulahanis* v. *Prevo's Family Market, Inc.*, 583 N.W.2d 509 (Mich. Ct. App. 1998), arose out of a sale of ground beef prior to the time that USDA declared such meat to be adulterated if it contains *E. coli*. But if the FMIA preempted state tort liability when the Secretary had not identified *E. coli* as an adulterant for *any* meat, then it follows *a fortiori* that tort liability must also be foreclosed for the sale of a category of meat — *i.e.*, intact cuts — for which the Secretary has maintained that position.

Meanwhile, respondents' characterization of *Grocery Manufacturers of America, Inc.* v. *Gerace*, 755 F.2d 993, *aff'd in relevant part*, 474 U.S. 801, *cert. denied in part*, 474 U.S. 820 (1985), is manifestly false. *Gerace* involved challenges to *both* an FDA regulation and a USDA interpretive rule; the Second Circuit extended *Chevron*-type deference to the former (*see id.* at 1001), but then independently analyzed and extended *Skidmore* deference to the latter (*see id.* at 1002 ("while we recognize that we are not bound by interpretive rules, we discern no reason to reject the USDA's longstanding interpretation of the FMIA") (citations omitted)).

And while *National Pork Producers Council* v. *Bergland*, 631 F.2d 1353 (8th Cir. 1980), and *Public Citizen* v. *Foreman*, 631 F.2d 969, 975 (D.C. Cir. 1980), involved formal rule-making, that in no way undercuts their basic points that Congress has granted the Secretary broad discretion to implement standards under the FMIA (*Bergland*, 631 F.2d at 1362), and that deference to her reasoned judgments is especially appropriate on issues "involving scientific and medical controversies" (*Foreman*, 631 F.2d at 975) — such as the very question at issue here.

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

RALPH A. WEBER
AMELIA L. MCCARTHY
SHAWN K. STEVENS
Gass Weber Mullins LLC
309 North Water Street
Milwaukee, WI 53202
(414) 223-3300

ANDREW J. PINCUS
Counsel of Record
RICHARD B. KATSKEE
Mayer, Brown, Rowe & Maw LLP
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

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MOTION FILED

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No. 03-862

In the Supreme Court of the United States

EXCEL CORPORATION,

Petitioner,

v.

ESTATE OF BRIANNA KRIEFALL, ET AL.,

Respondent.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE* AND BRIEF OF THE AMERICAN MEAT INSTITUTE, THE NATIONAL CHICKEN COUNCIL, THE NATIONAL FOOD PROCESSORS ASSOCIATION, THE NATIONAL MEAT ASSOCIATION, THE NATIONAL TURKEY FEDERATION, THE NORTH AMERICAN MEAT PROCESSORS ASSOCIATION, AND THE SOUTHWEST MEAT ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

ROY T. ENGLERT, JR.*
ALAN E. UNTEREINER
ALISON C. BARNES
Robbins, Russell, Englert, Orseck & Untereiner LLP
1801 K Street, N.W.
Suite 411
Washington, D.C. 20006
(202) 775-4500

* *Counsel of Record*

MOTION FOR LEAVE TO FILE BRIEF AS *AMICI CURIAE*

Under Rule 37.2 of the Rules of this Court, the American Meat Institute, the National Chicken Council, the National Food Processors Association, the National Meat Association, the National Turkey Federation, the North American Meat Processors Association, and the Southwest Meat Association move for leave to file the accompanying brief in support of the petition for a writ of certiorari. Counsel for petitioner has consented to the filing of this brief, but counsel for certain of respondents have declined to grant consent.

The issue presented by the petition – whether the Food Safety and Inspection Service, acting on delegated authority from the U.S. Secretary of Agriculture, is "powerless" (Pet. App. 19a) to decide that there is a distinction between intact and non-intact meat in deciding what meat is "adulterated" under the Federal Meat Inspection Act (FMIA) – is of profound importance to the meat and poultry industry and to consumers nationwide. Members of *amici curiae* include hundreds of meat processors and packers that are subject to pervasive federal regulation, including mandatory continuous inspection, by the U.S. Department of Agriculture (USDA) or state programs that USDA deems at least equivalent. Under the Wisconsin Court of Appeals' novel interpretation, members of *amici curiae* are subject to civil and criminal liability for supplying meat that complies fully with federal requirements. *Amici curiae* are well situated to assist the Court in understanding the enormous practical importance of the FMIA issue presented.

Amicus curiae American Meat Institute (AMI) is a national trade association representing packers, processors, suppliers, and distributors of meat and meat food products. AMI has been a force in the meat processing community since 1906 – the year the first federal meat inspection statute was passed.

Amicus curiae National Chicken Council (NCC) is a national, nonprofit trade association representing the chicken industry, including producers, processors, and distributors of chicken and chicken products. NCC members account for more than 95 percent of the chicken produced in the United States.

Amicus curiae National Food Processors Association (NFPA) is the principal scientific and technical trade association

for the food industry. NFPA members process and package fruits, vegetables, meat, fish, and speciality food products.

Amicus curiae National Meat Association (NMA) is a national trade association that has been advocating the interests of the meat industry since 1946. NMA members include packers, processors, and distributors of meat and meat products.

Amicus curiae National Turkey Federation (NTF) is the only national trade association representing the turkey industry exclusively. NTF represents more than 95 percent of the turkey industry in the United States, including breeders, hatchery owners, growers, and processors.

Amicus curiae the North American Meat Processors Association (NAMP) – founded in 1942 – is an international, not-for-profit trade association representing the needs of meat, poultry, seafood, and game processors.

Amicus curiae Southwest Meat Association (SMA) is a trade association representing packers and processors of meat and meat food products. SMA's members are located in Texas, Louisiana, Oklahoma, Arkansas, and New Mexico.

Amici – who collectively represent more than 95 percent of all companies engaged in processing beef, chicken, turkey, pork, lamb, and veal products in the United States – have a strong interest in persuading this Court to grant review, given the detrimental effect the Wisconsin Court of Appeals' decision, if allowed to stand, would have on the meat processing industry. The court below disregarded some of the FMIA's principal purposes as well as the enormous harm to the industry that would result from the court of appeals' decision to strip the Secretary of Agriculture of her power to interpret the FMIA's key term – "adulterated." In reaching its decision, the court completely disregarded the contradictory interpretation reached by the Secretary as well as scientific research supporting the Secretary's view. The court's approach was wrong and in conflict with this Court's teachings. See *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 842-843 (1984) (holding that a court should take an administrative interpretation of an ambiguous statutory term into account); *Alaska Dep't of Envtl. Conservation* v. *EPA*, 2004 WL 86284, *16 (U.S. Jan. 21, 2004) ("We normally accord particular deference to an agency interpretation

of long-standing duration, recognizing that well-reasoned views of an expert administrator rest on a body of experience and informed judgment to which courts and litigants may properly resort for guidance.") (internal citations and quotations omitted).

Members of *amici* are subject to the FMIA and its implementing regulations when engaged in their core business of meat processing and packing. And, if this Court denies review, they will be faced with possible civil and criminal penalties for distributing products that comply with USDA standards and pass federal inspection. Such a sweeping invalidation of the Secretary's longstanding, sophisticated, and nuanced interpretation of "adulterated" is of great concern to *amici*, who respectfully submit that its implications are far reaching enough, and its incorrectness clear enough, to cry out for this Court's review. *Amici* should therefore be granted leave to file the attached brief.

Respectfully submitted.

ROY T. ENGLERT, JR.
Counsel of Record
ALAN E. UNTEREINER
ALISON C. BARNES
Robbins, Russell, Englert, Orseck & Untereiner LLP
1801 K Street, N.W.
Suite 411
Washington, D.C. 20006
(202) 775-4500

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BRIEF OF *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*[1]

The interest of the *amici curiae* is described in the accompanying motion for leave to file this brief.

STATEMENT

The decision reached by the Wisconsin Court of Appeals – that any raw meat containing natural pathogens such as *E. coli* O157:H7 bacteria is adulterated and therefore unfit for human consumption – directly contradicts applicable U.S. Department of Agriculture (USDA) standards. The lower court's complete disregard for the expert agency's views calls into question the continuing power of the federal government to set the standards for meat sold in interstate commerce, opens the door for States to adopt widely varying and inconsistent interpretations of the Federal Meat Inspection Act, and undermines the extensive – and nationally uniform – system of federal meat inspection and oversight that has been in place for decades pursuant to Congress's desire to "prevent and eliminate burdens upon [interstate or foreign] commerce" while *also* protecting consumer health. 21 U.S.C. § 602.

A. Federal Regulation Of The Meat Industry

For nearly a century, federal authorities have been responsible for helping to ensure the safety of the Nation's food supply through (among other things) prevention of the sale of "adulterated" food products.[2] The meat industry – including

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amici* state that no counsel for a party has written this brief in whole or in part and that no person or entity, other than the *amici*, their members, or their counsel, has made a monetary contribution to this brief.

[2] In 1906, in response to publication of Upton Sinclair's famous book *The Jungle* (a graphic exposé of unsanitary conditions prevalent in the meat industry), Congress passed two statutes – the Pure Food and Drugs Act and the Federal Meat Inspection Act – that prohibited the sale of

entities involved in all aspects of meat preparation, from slaughter of livestock to sale of meat in retail establishments – is subject to the Federal Meat Inspection Act (FMIA or Act), 21 U.S.C. §§ 601-695, which establishes a comprehensive, uniform, national system for oversight of the preparation and sale of meat food products.

In enacting the FMIA, Congress recognized the importance of meat to the Nation's food supply and the dangers associated with insufficient oversight:

> Unwholesome, adulterated, or misbranded meat and meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. * * * [R]egulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

21 U.S.C. § 602. Since the Act's passage in 1906, Congress has amended it repeatedly – most significantly in 1967 – to ensure that the federal system is up to date and to withdraw all but the most limited power from the States. See 60 Fed. Reg. 6774, 6776 (Feb. 3, 1995) (describing the history of the FMIA).

The FMIA strives to accomplish all these objectives simultaneously by, among other things, prohibiting the sale of "adulterated" meat. 21 U.S.C. § 602. It defines "adulterated," in pertinent part, as follows:

"adulterated" food. See James Harvey Young, *The Long Struggle for the 1906 Law*, FDA CONSUMER, June 1981, *available at* http://vm.cfscan.fda.gov/~lrd/history2.html.

> The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:
>
> (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;
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> (2)(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance * * * which may, in the judgment of the Secretary, make such article unfit for human food;
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> * * *
>
> (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; [or]
>
> (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to the health.

21 U.S.C. § 601(m); see also 9 C.F.R. § 301.2 (adopting paragraphs (1), (3), and (4) of the definition of "adulterated").

To prevent adulterated meat from entering the food supply, Congress created a detailed, extremely intrusive federal oversight and inspection system and placed the responsibility for it in the hands of the Secretary of Agriculture, who in turn has delegated authority to the Food Safety and Inspection Service (FSIS). See 21 U.S.C. §§ 603, 604, 606, 608, 621, 678; 7 C.F.R. § 2.53(a)(2)(ii). In addition, Congress charged the Secretary with broad responsibility for establishing rules and regulations under the Act. See, *e.g.*, *id.* §§ 602, 608, 621.

Pursuant to that authority, the Secretary – among other things – prescribes rules regarding manufacturing processes and pace, sets plant sanitation standards, and employs agents at *each and every* federally inspected establishment to inspect meat at various stages of the preparation process. 60 Fed. Reg. at 6775; see generally 21 U.S.C. §§ 603-610, 612-613, 615; 9 C.F.R. §§ 307.1-.5, 310.1, 416.2-.6; 61 Fed. Reg. 38,806, 38,855 (July 25, 1996). Federal inspectors ensure compliance with the agency's sanitation standards, and refuse to allow the sale of meat products from facilities that fail inspection. 21 U.S.C. § 608.

Petitioner and members of *amici* are not merely subject to federal standards; they must have federal inspectors in their plants to examine livestock before slaughter, carcasses after slaughter, and meat products before distribution. See Pet. 5 (citing 60 Fed. Reg. at 6775-6777). The inspectors' organoleptic inspections (using sight, touch, and smell), which have been employed by federal inspectors for decades, are supplemented by sampling and statistical process methods identified in each facility's individualized plan.[3] Report to Cong. on the Consumer Safety Officer Initiative (FSIS Feb. 15, 2000), *available at* http://fsis.usda.gov/oa/congress/cso_report.htm. All "products found not to be adulterated" by the inspectors are marked "[i]nspected and passed," while all "products found

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[3] These plans – called Hazard Analysis and Critical Control Point (HACCP) plans – are hazard analysis systems that promote food safety by methodically identifying specific hazards in advance of processing so that they may be controlled. DENNIS R. JOHNSON & THE FOOD INSTITUTE, HACCP & U.S. FOOD SAFETY GUIDE § 5.3 (1996). In the late 1990s, the Secretary required each federally inspected plant to conduct a "hazard analysis" to "determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to reduce those hazards." 9 C.F.R. § 417.2(a). Each plant was then required to submit a written plan. *Id.* §§ 417.2-.3, 417.8 Plans accepted by USDA function like regulations in that all products from a noncompliant facility can be deemed "adulterated." *Id.* § 417.2(e).

adulterated" are marked "[i]nspected and condemned." 21 U.S.C. § 606. Those who violate the Act or USDA's regulations are subject to civil and criminal liability as well as a vast array of administrative sanctions, including the seizure and condemnation of meat and the withdrawal of federal inspection at an offending facility (thus shutting it down). *Id.* §§ 671-676.

In sharp contrast to the Secretary's broad power, the States' power is extremely limited: the Secretary and the States share power over products that are "adulterated or misbranded" under the federal scheme and that have left processing plants; and the States are permitted to have their own inspection programs if they are "at least equal to" federal standards. *Id.* §§ 661(c), 678,. Importantly, any state requirement that is "in addition to, or different" from, those issued by the Secretary is expressly preempted. *Id.* § 678.

B. Foodborne Diseases and *E. Coli* O157:H7

The United States' food supply is extremely safe, but foodborne diseases will always present challenges to our national food safety system. Institute of Food Technologists, *IFT Expert Report on Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century* (IFT Report), March 2002, *available at* http://www.ift.org/pdfs/microfs/webreport.pdf.[4] Microbiological disease-causing organisms such as *E. coli* are among the hardest sources of foodborne illness to detect and control.

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[4] In its report (at 4), the Institute of Food Technologists explains:

> Foodborne illness is not a simple problem in need of a solution; it is a complex combination of factors that must be managed on a continual basis. Aside from the inherent ability of pathogens themselves to evolve, pathogens' victims and the microbial environment play a role in the changing nature of foodborne illnesses, opening new niches and creating new vulnerabilities. No matter how sophisticated and complex a system is developed, food safety management is never finished or complete, because change is constant.

Like many pathogens, *E. coli* is a species of bacteria that naturally exists in warm-blooded animals, usually without causing illness to the host. Pet. 8; IFT Report at 27. The type of *E. coli* at issue in this case – O157:H7 (hereinafter *E. coli* O157) – is an elusive and virulent strain first reported as a foodborne pathogen in 1982. *Ibid.* And, although it is estimated that as many as half of all cattle carry *E. coli* O157 at some time in their lives, there is nevertheless a "low incidence of disease" associated with this bacterium. *Id.* at 28.

Despite that low incidence of disease, USDA and other public health organizations have long recommended that consumers take steps to protect themselves from illness caused by *E. coli* O157. To that end, federal authorities have repeatedly explained that proper cooking kills harmful bacteria in meat products (see Pet. 8), and have consistently advised consumers of the need to wash any dish, utensil, or surface that comes into contact with raw meat to prevent cross-contamination. See 9 C.F.R. § 317.2(1) (requiring proper handling and safe cooking instructions on labels of packaged raw meat); http://www.cdc.gov/ncidod/dbmd/diseaseinfo/escherichiacoli_g.htm.

In 1994, USDA decided to take an additional protective measure: it declared *ground* beef containing *E. coli* O157 to be "adulterated" within the meaning of the FMIA, and began testing ground beef samples for the presence of this bacterium. See 67 Fed. Reg. 62,325, 62,326 (Oct. 7, 2002). USDA announced that ground meats containing *E. coli* O157 are adulterated, whereas intact cuts of meat bearing *E. coli* O157 are not. 64 Fed. Reg. 2804 (Jan. 19, 1999).[5]

Since that pronouncement, USDA has continued to gather information about *E. coli* O157 and its prevalence in meat. Recent scientific research and improvements in testing

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[5] The Secretary recently reaffirmed the safety of properly cooked intact cuts of meat, describing the risk of illness associated with *E. coli* O157 as "minuscule, regardless of the initial contamination level or susceptibility of the consumer." 67 Fed. Reg. 62,334 (Oct. 7, 2002).

techniques have led the agency to conclude that the bacterium is more common than previously thought. 67 Fed. Reg. 62,326. Consequently, in 2002, the FSIS instructed federally inspected processing plants to reassess their HACCP plans to ensure that they include measures designed to "prevent, eliminate, or reduce the presence of *E. coli* O157:H7 in their products." *Id.* at 62,332. Significantly, however, the Secretary left unchanged the rule that intact meat bearing *E. coli* O157 is not adulterated.[6]

C. The Proceedings Below

This case arises from injuries suffered by patrons of an E&B Sizzler restaurant who allegedly ate food from the salad bar that had become cross-contaminated with *E. coli* O157. Pet. 11. Respondents filed a common law tort action against numerous parties, including petitioner Excel Corporation.

Excel supplied intact cuts of raw meat to the Sizzler franchise at issue. Pet. App. 10a-11a. Before leaving Excel's facility, the meat had passed USDA inspection and was labeled with safe handling instructions. See *id.* at 17a.

Excel was granted summary judgment in the trial court. Pet. App. 52a. The court relied on the Secretary's determination that intact meat containing surface *E. coli* O157 is not adulterated within the meaning of the FMIA. Pet. App. 48a-49a. The trial court ruled that the Act and its comprehensive regulatory scheme preempt contrary state laws, including "civil suits against meat processors like Excel." *Id.* at 50a.

The Wisconsin Court of Appeals reversed, holding that intact cuts of meat containing *E. coli* O157 are adulterated. Pet. App. 19a-27a. The court of appeals arrived at that conclusion after determining that no deference would be given to the Secre-

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[6] Contrary to the lower court's suggestion (Pet. App. 35a), the Secretary has never ruled that *E. coli* O157 must be eliminated altogether from meat processing facilities and meat products. She has ruled, however, that inspectors must have "zero tolerance" for visible contaminants. See Pet. 10 n.2.

tary's rules regarding *E. coli* O157 because Congress delegated no power to interpret the statutory term "adulterated" to the Secretary (except in one limited area not applicable to this case). *Id.* at 13a, 16a, 19a. Without taking either the Secretary's views or longstanding industry practice into account, the appellate court concluded that any cut of meat containing any *E. coli* O157 is adulterated and unfit for human consumption. Pet. App. 14a. The state supreme court denied review without explanation. *Id.* at 44a.

SUMMARY OF ARGUMENT

I. This Court has jurisdiction, under 28 U.S.C.§ 1257, to review the Wisconsin Court of Appeals' decision that USDA is "powerless" (Pet. App. 19a) to interpret the meaning of "adulterated" under the FMIA. See *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 477 (1975). The decision below is the last word from a state court on an important federal issue that is potentially dispositive – indeed, *was* dispositive in the trial court – of the claims against petitioner. If review is denied, there may be no subsequent opportunity for this Court to address the court of appeals' decision because petitioner may prevail on non-federal grounds.

II. Review should be granted to protect the meat industry and consumers from the drastic consequences that would ensue if this nonsensical decision were permitted to stand. Apparently deeming itself better situated to interpret the non-self-defining term "adulterated" than the agency that has been regulating meat for 98 years, the Wisconsin Court of Appeals has disregarded the statutory and regulatory framework of the FMIA as well as years of experience and research by writing out of existence USDA's interpretation of "adulterated" – the single most important term in the FMIA – and replacing it with an unscientific and rigid interpretation of the statute. The court's reading destroys the national uniformity Congress intended to create and invites States to adopt interpretations of the FMIA that are in conflict.

To avoid potential liability, meat producers may have to comply – to the extent that they can – with divergent (and perhaps conflicting) standards from across the country, many of which – like the court of appeals' – would lack a valid scientific basis. The potential for harm – to meat processors and packers, including members of *amici*; to purchasers of meat products, including wholesalers, retailers, and restaurants that resell meat products; to consumers themselves; and to interstate commerce and the national economy – is difficult to overstate. The danger of the potential harms can be avoided only if the court of appeals' decision is reversed.

ARGUMENT

I. THIS COURT HAS JURISDICTION TO REVIEW THE WISCONSIN COURT OF APPEALS' DECISION

This Court's certiorari jurisdiction over decisions of the state courts is conferred by 28 U.S.C. § 1257, which authorizes review of any "[f]inal judgment[] or decree[] rendered by the highest court of a State in which a decision could be had."[7] The Court has long eschewed a "mechanical" interpretation of the requirement of "finality." *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 477 (1975). Instead, the Court has applied an "intensely practical approach" to determining "finality." *Mathews* v. *Eldridge*, 424 U.S. 319, 332 n.11 (1976); see also *Cox Broadcasting*, 420 U.S. at 478 & n.7 ("[T]he requirement of finality is to be given a practical rather than a technical construction.") (internal quotations omitted). See generally STERN & GRESSMAN at 145, 152-154.

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[7] The judgment of an intermediate state court is reviewable under 28 U.S.C. § 1257 when the highest state court declines to take the case. See ROBERT L. STERN, EUGENE GRESSMAN, STEPHEN M. SHAPIRO & KENNETH S. GELLER, SUPREME COURT PRACTICE 163, 165-167 (8th ed. 2002) (STERN & GRESSMAN).

In *Cox Broadcasting*, this Court noted four categories of cases in which it has treated decisions of the state courts as "final" even though "there [we]re further proceedings in the lower state courts to come." 420 U.S. at 477. As petitioner correctly points out (Pet. 16 n.4), this case falls squarely within the fourth category: cases in which (1) "the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court"; (2) "reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come"; and (3) "a refusal immediately to review the state court decision might seriously erode federal policy." 420 U.S. at 482-483.

Each of those conditions is satisfied here. *First*, the Secretary's power to interpret the critical term "adulterated" under the FMIA was fully considered – and squarely resolved – below. And, if review is denied, it is possible that petitioner eventually will prevail on the merits on nonfederal grounds. See Pet. App. 4a ("We conclude that federal preemption does not close the doors of Wisconsin's courts to the claims against Excel; the merits of those claims still have to be determined.").

Second, if this Court were to reverse the decision below by holding that the Secretary's interpretation of "adulterated" is entitled to judicial respect, respondents' claims against petitioner could be finally resolved. That is precisely what the trial court decided, which led that court to enter judgment for petitioner on all claims against it. Pet. App. 52a-54a.

Third, the federal policy underlying the FMIA and its preemption clause would be seriously undermined if this Court declines to exercise immediate review. As its title suggests, the FMIA, including its express preemption clause, is aimed at ensuring nationwide uniformity in the standards for meat

produced for human consumption. See 21 U.S.C. § 602. The decision below destroys that uniformity by allowing state courts – and possibly state regulators as well – to impose additional or different requirements on meat producers.

In similar circumstances, this Court has repeatedly applied *Cox Broadcasting* to grant immediate review. See, *e.g.*, *Mississippi Power & Light Co.* v. *Mississippi*, 487 U.S. 354, 270 n.11 (1988) (explaining that the "critical federal question" was "ripe for review" even though a state court had decided the federal preemption question and remanded for further proceedings); *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174, 179-180 (1988) (granting review of a federal preemption question despite the pendency of additional state proceedings because leaving the state decision unreviewed would have threatened to undermine vital federal policies); *Southland Corp.* v. *Keating*, 465 U.S. 1, 6-7 (1984) (reviewing a state-court decision regarding federal preemption, even though claims had not yet been tried on the merits); *Belknap, Inc.* v. *Hale*, 463 U.S. 491, 497 n.5 (1983); *Local No. 438 Constr. & General Laborers Union* v. *Curry*, 371 U.S. 542, 548-551 (1963).

II. IF LEFT UNDISTURBED, THE COURT OF APPEALS' DECISION WOULD HAVE SERIOUS, HARMFUL, AND UNJUSTIFIED EFFECTS ON THE MEAT INDUSTRY AND CONSUMERS

The Wisconsin Court of Appeals failed to appreciate the magnitude and probable effects of its decision not only to strip the Secretary of her power to interpret key provisions of the FMIA but also to adopt a new judicial definition of "adulterated" without the benefit of the Secretary's experience, expertise, and guidance. The decision below does violence to the comprehensive, longstanding system of federal regulation in this area by eliminating the Secretary's power to interpret many provisions in the FMIA, leaving courts and state regulators to reach their own conclusions, and creating a regulatory leadership void in this important national industry. Failure to review it would result in the absence of the clarity, uniformity, and efficacy that

the statute plainly seeks and the current scheme provides. And the resulting uncertainty and inevitable confusion would adversely affect the price and availability of meat, and would lead to a fragmented, decentralized system under which the Nation's food supply will be *less* – not more – safe.

A. The Decision Below Would Destroy The Uniformity And Certainty That The Current System Was Designed To – And Does – Provide

Much of the statutory and regulatory structure of the FMIA turns on the interpretation of the term "adulterated." Under the FMIA, "adulterated" is the term used to describe meat that, for various reasons, must be condemned and destroyed. 21 U.S.C. §§ 604, 606. Meat that is deemed adulterated cannot be shipped or sold under the Act. *Id.* § 601. Processors who ship or sell adulterated meat face potential civil and criminal liability under federal law (*id.* §§ 671-676), and under state law (see *id.* § 678). See *Armour & Co.* v. *Ball*, 468 F.2d 76, 84 (6th Cir. 1972), cert. denied, 411 U.S. 981 (1973).

The meaning of "adulterated," however, cannot be gleaned from the statute alone. Indeed, the statutory definition of this crucial term encompasses meat that is "injurious to health," "filthy, putrid, or decomposed," or "insanitary," (21 U.S.C. § 601(m)(1), (3), (4)) – all terms whose meaning is far from clear from text alone unguided by science or experience. Despite the statute's lack of *textual* clarity, the meaning of "adulterated" was perfectly clear until the court of appeals issued its jarring decision: it was exactly as the Secretary prescribed based on experience and careful attention to the statute's various goals, including the protection of interstate commerce. Indeed, meat processing facilities across the country – as well as federal inspectors – have, until now, faithfully applied the Secretary's interpretation. Without the Secretary's guidance, meat processors could not possibly have predicted what would constitute "adulterated" meat.

Yet that is exactly the situation that meat processors will face if the decision below stands. If unable to rely on the Secretary's interpretation of "adulterated," meat processors are faced with great uncertainty – and enormous potential liability – regarding their production and sale of meat that USDA deems *un*adulterated. The court of appeals' decision opens the door to courts and regulators in other States to reach their own decisions regarding the meaning of "adulterated" and other key FMIA terms. It thus creates the distinct possibility that meat processors will be subject (after the fact) to as many as fifty sets of standards, some of which may conflict – as the standard adopted below does – with interpretations from the federal government and other States. Such a fragmented and decentralized scheme is perilous for a meat processor trying to ensure that its products comply with the laws.

Meat processors would not be the only group with this problem. Poultry and egg producers – who are subject to statutes with similar or identical language – may very well face the same dilemma. See Pet. 25-26 (citing the Poultry Products Inspection Act (PPIA), 21 U.S.C. §§ 451-471); Egg Products Inspection Act, 21 U.S.C. §§ 1031-1056. That is why *amici* representing the poultry industry join this brief.

Congress did not envision such a decentralized system, as the FMIA itself reveals. In the statute, Congress delegated to the Secretary the responsibility for prescribing certain rules and regulations (21 U.S.C. §§ 602, 608), for implementing and conducting on-site federal inspections (*id.* §§ 603, 604, 606, 621), and for taking action against violators of the statute and USDA regulations (*id.* §§ 671-676). Congress also prohibited States from imposing requirements that are "in addition to, or different" from, federal requirements imposed under the FMIA. See *id.* § 678; *National Broiler Council* v. *Voss*, 44 F.3d 740 (9th Cir. 1994) (holding that the PPIA and USDA's policy statements interpreting it preempted inconsistent state labeling laws); Letter from Richard E. Lyng, Sec'y of Agric., to George Deukmejian, Governor of Cal. (June 12, 1987) ("regulation by

the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated [in the FMIA and PPIA] are appropriate to prevent and eliminate burdens upon and effectively regulate [interstate and foreign] commerce as well as to protect the health and welfare of consumers (21 U.S.C. 451 and 602)"). These provisions indicate Congress's unmistakable intent to develop a detailed and uniform regulatory regime administered by the Secretary. Indeed, establishing uniform national requirements and preventing States from enforcing their own standards were the motivations for the 1967 amendments to the FMIA. See 60 Fed. Reg. 6774 ("The Wholesome Meat Act of 1967 * * * amended the basic laws governing mandatory meat * * * inspection to assure uniformity in the regulation of products shipped in interstate, intrastate, and foreign commerce."). The court of appeals' decision threatens to disassemble this regime.

The comprehensive federal regulatory regime that has developed serves its purpose well. Under the current scheme, approximately 7000 federal inspectors are stationed at thousands of federally inspected establishments. See Meat and Poultry Inspection: Report of the Sec'y of Agric. to the U.S. Cong. (Fiscal Year 2000) (FSIS Feb. 15, 2003), at 47, *available at* http://fsis.usda.gov/oa/congress/congress.htm. These inspectors monitor the slaughter and preparation of all meat and poultry products prepared for interstate commerce to ensure safety, wholesomeness, and accurate labeling and packaging. *Ibid.* In Fiscal Year 2000, FSIS inspected nearly 134 million head of livestock and more than 8.5 billion birds, and detained nearly 28 million pounds of adulterated meat and poultry products. *Id.* at 47, 35. The inspectors throughout the country conducted their inspections with a common understanding of the terms of the FMIA, including "adulterated." In the wake of the court of appeals' ruling, the certainty resulting from federal inspections would be abolished. Indeed, the definition of "adulterated" used by federal inspectors might bear little resemblance to the interpretation given to the term by officials in the State where

a cut of meat is eventually shipped or sold. Under that scenario, federal inspection is cold comfort to meat processors.

The court of appeals' decision also calls into question the Secretary's ability to set national priorities for the meat industry. Historically, the Secretary has been able to guide the meat industry by passing nationally implemented regulations and issuing informal guidance to facilities across the country. In response to those directives, meat processors have shifted resources towards the priorities set by the Secretary. See, *e.g.*, 67 Fed. Reg. 62,326 (interpretation designed to limit the prevalence of *E. coli* O157 in ground beef). The court of appeals' decision severely undercuts the Secretary's prospective ability to set national priorities for the meat industry. And, in light of the ever-present threat of terrorist actions against our national food supply[8] and the recent discovery of the first U.S. case of bovine spongiform encephalopathy (mad cow disease), the need for strong centralized authority could not be greater.[9]

By reading the FMIA in a way that eliminates USDA's power to interpret it, the court of appeals invites States to set their own food safety priorities. And those priorities, which would inevitably reflect local – not national – concerns, would lead to the demise of the national regulatory system.

B. The Decision Below Would Increase Cost and Confusion Without A Corresponding Improvement In Food Safety

If the meat industry adopts the court of appeals' interpretation of "adulterated" – as it may be forced to do if review

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[8] See FSIS Directive 5420.1 (March 17, 2003), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5420_1.pdf (explaining procedures in the event of a terrorist threat to the Nation's food supply).

[9] Federal initiatives designed to control the spread of mad cow disease – including the creation of a national cattle tracing system – can be accomplished only at the national level. See Margaret Webb Pressler, *Cattle-Tracing System Will Face Obstacles*, WASH. POST, Jan. 3, 2004, at E1.

is not granted – the effects on the meat industry and consumers will be significant. The court of appeals' decision would replace uniformity and predictability with uncertainty and confusion, leading to a decrease in the availability and affordability of meat products, hardship for the meat industry, and a less safe national meat supply. The court of appeals was wrong to believe that its interpretation of "adulterated" would serve the supposedly "overriding congressional purpose" of "public safety" (Pet. App. 10a).

To comply with the court's interpretation of "adulterated," all entities that sell meat – including slaughterhouses, meat processing plants, wholesalers, and retail establishments – would have to change complex production processes – even though such measures cannot guarantee that no *E. coli* O157 (or other natural pathogens) will exist on the meat when it reaches the ultimate consumer. Changes in the production process would raise production costs and lengthen production time. As a practical matter, the court of appeals' decision would mean that processing facilities would have to purchase the same number of animals, and run the same number of production lines, but would end up with fewer "unadulterated" cuts of raw meat (even though the "adulterated" meat poses little or no health risk). With higher costs and less product to sell, the industry – already known for its low profit margins[10] – would face even lower profitability, putting the entire industry in economic straits.

The increases in production costs that would be necessitated by the court's decision would inevitably be passed on to the consumer. *See* USDA, *Assessment of the Cattle and Hog Industries*, Calendar Year 2001 (2001 Assessment), 5, *available at* http://www.usda.gov/gipsa/pubs/01assessment/01assessment.pdf ("Retail prices reflect the total cost of producing, processing, distributing, and marketing meat and poultry products."). And all of this would occur at a time when the cost of beef is at

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[10] See Pressler, *supra* note 9, at E1.

an all-time high and the supply is at a seven-year low. See Blaine Harden, *Protein Diet Craze, Thin Supply of Cattle Fatten Ranchers' Wallets*, WASH. POST, Dec. 22, 2003, at A1. Cost increases could adversely affect consumers' ability to buy meat, leading to decreased consumption of it, especially in poorer segments of the population. See 2001 Assessment at 5 (changes in meat prices affects per capita consumption). And decreasing meat consumption can have negative nutritional and health consequences. See Fiona Bushell, *Food, Food, Food*, ENVTL. HEALTH J., Dec. 2001, *available at* http://www.ehj-online.com/archive/2000/december2001/december4.html.

C. The Decision Below Lacks A Valid Scientific Basis

What makes this parade of horribles all the worse is that there is no sound scientific basis for the Wisconsin Court of Appeals' approach. The court simply determined, without the benefit of expert, industry, or USDA assistance, that *E. coli* O157 on raw intact meat renders that meat "adulterated" because the bacteria *may* cause injury. Pet. App. 14a. The Secretary's interpretation, in contrast, is the product of cutting-edge scientific research and reasoned debate.

There is no valid scientific basis for the court's conclusion that raw intact cuts of meat with *E. coli* O157 present a significant health risk. The risk of illness from intact meat bearing *E. coli* O157 is "minuscule, regardless of the initial contamination level or susceptibility of the consumer," when the meat is adequately cooked. 67 Fed. Reg. 62,334; see also IFT Report at 27-28 (reporting a "low incidence of disease" associated with *E. coli* O157).[11] This scientific information formed the basis of the Secretary's decision to declare *E. coli* O157 an adulterant in ground – but not intact – beef products. See 64 Fed. Reg. 2804. Indeed, the Secretary explained that she

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[11] Indeed, the real problem – and the one that occurred in this case – is that preparers of raw meat often fail to take the recommended precautions to prevent cross-contamination. See Amanda Hesser, *Squeaky Clean? Not Even Close*, N.T. TIMES, Jan. 28, 2004, at D1.

"carefully considered the deliberations of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)" – an entity that makes scientific recommendations for the benefit of FSIS and the FDA[12] – before reaching the conclusion that "cuts of intact muscle (steaks) should be safe" if cooked properly because there is "a low probability of pathogenic bacteria being present in or migrating from the exterior surface to the interior of the beef muscle." *Id.* at 2803.

As it did when developing that standard, USDA continually monitors scientific developments and formulates reasoned approaches designed to control or, when possible, eliminate foodborne pathogens, which continue to evolve and mutate. The FSIS described its approach as follows:

> The Agency's continuing goal is to focus its efforts on addressing the true human health risks associated with meat, poultry, and egg products, as has been recommended by the National Academy of Sciences. We believe that this is best approached using a farm-to-table approach to microbial risk assessment to identify significant food safety hazards and identify potential strategies to prevent, reduce, or eliminate those hazards. * * * FSIS is working with other agencies and institutions to develop appropriate quantitative risk assessment methods and to support studies to fill data gaps needed to enhance the precision and reduce the uncertainty in risk characterizations.

Report to Cong. on the Consumer Safety Officer Initiative (FSIS Feb. 15, 2000), *available at* http://fsis.usda.gov/oa/congress/cso_report.htm. In addition to its relationship with NACMCF, FSIS obtains valuable information from the Centers for Disease Prevention and Control, the FDA's Center for Safety and Applied Nutrition, USDA's Agricultural Research Service, and the National Institute of Allergy and Infectious Disease. See 67 Fed. Reg. at 62,325-62,334; see generally CENTER FOR SAFETY & APPLIED NUTRITION, FOODBORNE

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[12] JOHNSON, *supra* note 3, § 6.2.

PATHOGENIC MICROORGANISMS AND NATURAL TOXINS HANDBOOK, *available at* http://cfscan.fda.gov/~mow/chap15.html; National Institute of Allergy and Infectious Disease, *Foodborne Diseases*, April 2002, *available at* http://www.niaid.nih.gov/factsheets/foodbornedis.htm.

Unlike the Secretary's considered judgment, the court of appeals' conclusion is based on nothing more than a simplistic analysis of ambiguous statutory text. In a world where the elimination of all foodborne pathogens is impossible,[13] USDA does the next best thing: it uses cutting-edge scientific information to develop standards for acceptable levels of harmful bacteria.

D. The Decision Below Is Blatantly Incorrect Because It Fails To Defer To The Secretary And To Consider The Statutory Objectives Collectively

Petitioner has adequately demonstrated the error of the decision below, but *amici* add a few words. The Wisconsin Court of Appeals was wrong in failing to defer to the Secretary's interpretation of "adulterated." The absence of formal rulemaking was certainly no excuse for failing to defer. See *Alaska Dep't of Envtl. Conservation* v. *EPA*, 2004 WL 86284, *16 (U.S. Jan. 21, 2004) ("Cogent administrative interpretations * * * not [the] product of formal rulemaking * * * nevertheless warrant respect."); *United States* v. *Mead Corp.*, 533 U.S. 218, 234 (2001) (deference should be given to agency guidance, "given the 'specialized experience and broader investigations and information' available to the agency * * * and given the value of uniformity in its administrative and judicial understandings of what a national law requires") (citations omitted); *Schuetz* v. *Banc One Mortgage Corp.*, 292 F.3d 1004, 1012-14 (9th Cir. 2002) (granting deference to an agency's policy statements that were published in the Federal Register but not the subject of formal rulemaking or adjudication), cert. denied, 537 U.S. 1171 (2003).

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[13] See generally IFT Report at 1-12; JOHNSON, *supra* note 3, § 3.6.

Technicalities of the *Chevron/Mead* doctrine aside – and the court below did not purport to rest its judgment on any such technicalities – the decision below reflects a woeful failure to recognize the sometimes-competing policy aims that ambiguous statutory language often reflects and that federal agencies may and must reconcile in light of experience. The court below reasoned that "*[t]he* focus of" the relevant subsections "is on people's health and safety." Pet. App. 19a (emphasis added). That singular focus blinded the court to the other statutory objectives – namely, promoting the national market for wholesome meat and protecting the meat industry from losses. See 21 U.S.C. § 602. "Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice – and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *PBGC* v. *LTV Corp.*, 496 U.S. 633, 646-647 (1990) (quoting *Rodriguez* v. *United States*, 480 U.S. 522, 525-526 (1987)). So too in the area of administrative interpretations of statutes, when "Congress intended to accommodate [multiple] interests, but did not do so itself on the level of specificity presented by" a case, it is not the business of non-expert judges to reach their own preferred reconciliation, let alone to pretend that one statutory goal trumps all others. *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 865 (1984).

The Wisconsin court did violence to an effective and proven statutory and administrative scheme, and did so on the basis of its own simplistic statutory analysis. This Court should not allow that result to stand.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

ROY T. ENGLERT, JR.
Counsel of Record
ALAN E. UNTEREINER
ALISON C. BARNES
Robbins, Russell, Englert
Orseck & Untereiner LLP
1801 K Street, N.W.
Suite 411
Washington, D.C. 20006
(202) 775-4500

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No. 03-862

IN THE

Supreme Court of the United States

EXCEL CORPORATION,

Petitioner,

v.

ESTATE OF BRIANNA L. KRIEFALL, *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the Court of Appeals of Wisconsin

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF FOR PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF THE PETITION

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 22091
(703) 264-5300

JAMES M. BECK*
EDWARD T. FISHER
DECHERT LLP
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103-2973
(215) 994-2970
Attorneys for Product Liability Advisory Council, Inc.

* *Counsel of Record*

ST IVES BURRUPS/APPELLATE DIVISION, 1617 JFK BOULEVARD, PHILA., PA. 19103 (215) 563-9000

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE*

Pursuant to Rule 37.2 of the Rules of this Court, the Product Liability Advisory Council, Inc. ("PLAC"), moves for leave to file the accompanying brief as *amicus curiae* in support of the Petition for a writ of *certiorari*. Counsel for Petitioner has consented to the filing of the brief, but counsel for the Individual Respondents withheld consent.

PLAC is a non-profit association with 132 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to contribute to improvement and reform of the law governing the liability of product manufacturers in the United States and elsewhere. PLAC's perspective is derived from the experiences of diverse corporate members in industries spanning the manufacturing sector. In addition, several hundred leading product liability defense attorneys across the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 650 briefs as *amicus curiae* in both state and federal courts, including many in this Court, presenting the views of product manufacturers seeking fairness and balance in the application and development of the law affecting product liability. A list of PLAC's corporate members is found in the accompanying appendix.

PLAC believes that the decision of the Wisconsin Court of Appeals cries out for review. At issue is a federal statute, the Federal Meat Inspection Act ("FMIA"), that, among other things, uniformly bans "adulterated" meat from interstate commerce. The responsible federal agency, the United States Department of Agriculture ("USDA"), excludes from the definition of "adulterated" intact meat with certain types of bacteria, such as *E. coli*, on its surface. USDA does not view such meat as adulterated because these naturally occurring bacteria are ubiquitous and because they are easily killed when the meat is cooked before it is eaten.

The court below held USDA's interpretation invalid in Wisconsin. Meat that USDA allows in interstate commerce is now illegally "adulterated" in that state. The court gave USDA's interpretation of "adulterated" no deference because it held that USDA had no authority to construe this part of FMIA. Because one of the nine statutory definitions of "adulterated" expressly referred to administrative discretion, the court held by implication that Congress delegated no authority to USDA to construe the other eight definitions.

PLAC's members manufacture and distribute products for a nationwide market. The Wisconsin ruling threatens uniformity of federal regulation of many kinds of products. Important sections of almost every federal statute regulating product manufacturing could be similarly misconstrued because they likewise have some provisions expressly mentioning administrative discretion, and others that do not.

There is no basis to believe that absence of explicit reference to agency discretion at the level of a statutory subsection reflects congressional intent to deprive federal administrative bodies of discretion. No such intent appears in the legislative history of FMIA. To hold, as the Wisconsin court has here, that such omissions override general grants of administrative discretion and allow states free reign to adopt contrary interpretations of federal statutes would Balkanize the American economy.

PLAC's broad membership allows it to bring a perspective to this case transcending any particular industry or statute. Accordingly, PLAC seeks to submit the accompanying brief to inform the Court of the importance of the issues raised by the Petition, as they affect manufacturers of all federally regulated products, and of the adverse consequences that would flow from leaving those issues unreviewed.

For the foregoing reasons, PLAC's motion for leave to file the accompanying brief as *amicus curiae* in support of the petition for a writ of *certiorari* should be granted.

Respectfully submitted,

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 22091
(703) 264-5300

February 13, 2004

JAMES M. BECK*
EDWARD T. FISHER
DECHERT LLP
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103-2973
(215) 994-2970
Attorneys for Product Liability Advisory Council, Inc.

* *Counsel of Record*

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INTEREST OF THE *AMICUS CURIAE*[1]

The interest of the *amicus curiae* is described in the accompanying motion for leave to file this brief.[2]

INTRODUCTION AND SUMMARY OF ARGUMENT

The Court of Appeals of Wisconsin has ruled that Petitioner's meat products were "adulterated" under the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§601-95. The court rejected the position of the United States Department of Agriculture ("USDA"), the expert agency administering FMIA, that the meat was not adulterated. *Estate of Kriefall v. Sizzler USA Franchise, Inc.*, 665 N.W.2d 417 ¶¶20, 33 (Wis. App. 2003) (Pet. App. 19a, 30a).

The court concluded that USDA lacked discretion to interpret "adulterated," as defined in 21 U.S.C. §601(m), to exclude "intact" meat with *E. coli* bacteria on its surface. Ignoring FMIA's general grant of rulemaking authority, 21 U.S.C. §621, the court construed a single reference to "the judgment of the Secretary" in §601(m)(2)(A) to impliedly revoke USDA discretion as to every subsection of §601(m) that did not contain a similar reference (Pet. App. 19a ¶20).

This decision eviscerates FMIA's national meat safety standards. Since commerce in meat transcends state boundaries, a national standard for meat safety is necessary to protect public health. With Wisconsin unilaterally adopting an "adulteration" standard more restrictive and at odds with federal law, regulated meat suppliers such as Petitioner can no longer rely upon federal compliance to satisfy state obligations. While state regulation in this case

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1. Pursuant to Rule 37.6 of the Rules of this Court, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part and that no person or entity other than *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

2. A list of the members of *amicus curiae* Product Liability Advisory Council, Inc. is in the attached Appendix.

takes the form of common-law tort litigation, the Wisconsin court's holding is not so limited. Should Wisconsin administrative agencies so choose, they may seize or exclude any meat not meeting the court's peculiar definition of "adulterated."

PLAC supports the Petition because the implications of a ruling unilaterally excepting Wisconsin from adherence to USDA's meat adulteration standards are staggering. Uniform federal product regulation has created integrated, national markets for many types of goods. As these statutes are successively amended, provisions added at different times often differ in what they say about administrative delegation.

The Wisconsin decision jeopardizes federal administrative authority at a fundamental level. By flatly denying delegation, it deprives federal administrative decisions of any deference. The assault thus sanctioned on federal regulatory authority acutely threatens regulation of other foods, drugs and cosmetics, since Congress coordinated FMIA's definition of adulteration with the Food, Drug & Cosmetic Act. However, almost every federal statute regulating products will be implicated if this decision is allowed to stand.

REASONS FOR GRANTING THE WRIT

I. THE UNIQUE INTERPRETATION OF "ADULTERATED," ADOPTED IN ORDER TO AVOID EXPRESS PREEMPTION OF RESPONDENTS' TORT CLAIMS, THREATENS THE VERY NATIONAL UNIFORMITY THAT FMIA PREEMPTION IS INTENDED TO PRESERVE.

Although the issue in the Petition is not federal preemption as such, the Wisconsin result cannot be understood except in that context. Preemption was the basis of the summary judgment order that the Wisconsin court overturned, and it lurks just beneath the surface throughout that court's opinion.

FMIA has an express preemption clause barring any state from imposing requirements that "are in addition to, or different than" those imposed by USDA. 21 U.S.C. §678. Concurrent federal-state enforcement is permitted if – but only if – a product is "adulterated or misbranded" under the federal USDA standards:

> [A]ny State. . .may. . .exercise concurrent jurisdiction with the Secretary over articles required to be inspected. . .for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded. . . . *Id.*[3]

Congress enacted this cooperative federal/state enforcement scheme to promote uniform regulation of meat. "States would be precluded from imposing additional or different. . . requirements for federally inspected products. Both industry and consumers would benefit from. . .greater uniformity." H.R. Rep. No. 1333 (1968), *reprinted in,* 1968 U.S.C.C.A.N. 3426, 3442. "Federal standards must be

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3. The Wisconsin court "assumed" applicability of §678 to this action (Pet. App. 6a n.3).

required of all meat and meat food products." S. Rep. No. 799 (1967), *reprinted in,* 1967 U.S.C.C.A.N. 2188, 2191.

State enforcement – including state common law actions – survives FMIA express preemption only where meat fails applicable federal standards. In *Jones v. Rath Packing Co.,* 430 U.S. 519 (1977), a state statute rigidly prohibiting weight decrease from moisture loss was preempted by FMIA regulations that allowed "reasonable" variations from labeled weights. Thus, in *Jones,* compliance with the federal standards, *id.* at 528, precluded different, more stringent state-law standards. The Court "conclude[d] that with respect to [the] packaged bacon, [the state provisions] are pre-empted by federal law." *Id.* at 532.

Both before and after *Jones,* other courts in FMIA cases unanimously concluded that USDA standards define the scope of FMIA preemption. Where meat is "adulterated" or "misbranded" for violating USDA requirements, states are not precluded from – and, indeed, are encouraged to – independently enforce the federal standards.[4] Conversely, additional or divergent state standards are preempted where a meat product complies with all relevant federal requirements.[5] Federal preemption under FMIA applies

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4. *Swift & Co. v. Walkley,* 369 F. Supp. 1198, 1199-1201 (S.D.N.Y. 1973) (state enforcement allowed where USDA "acknowledged to [state] officials that it was in error in approving [the] labels"); *People v. Rath Packing Co.,* 149 Cal. Rptr. 431, 443 (Cal. App. 1978) (state may impose additional penalties upon meat not conforming to federal standards).

5. *Grocery Manufacturers of America, Inc. v. Gerace,* 755 F.2d 993, 1003 (2d Cir. 1985) (state "requirements d[id] not comport exactly with the federal specifications, [and t]herefore. . .[we]re preempted"), *aff'd mem.,* 474 U.S. 801 (1985), *cert. denied,* 474 U.S. 820 (1985); *Armour & Co. v. Ball,* 468 F.2d 76, 84 (6th Cir. 1972) ("[i]n its concurrent enforcement a state would not be permitted to prevent the distribution in commerce of any article that 'conforms' to the [federal standard]"), *cert. denied,* 411 U.S. 981 (1973); *Kraft Foods North America, Inc. v. Rockland County Dept. of Weights and Measures,* No. 01 CIV. 6980 (WHP), 2003 WL 554796, at *7 (S.D.N.Y. Feb. 26, 2003) (state-law "inspection practices impermissibly 'differ from' and are 'contrary to'" FMIA requirements); *Cook Family Foods, Ltd. v. Voss,* 781 F. Supp. 1458, 1465-68 (C.D. Cal.

against private tort or contract actions under state law, as well as against state administrative action.[6]

Preemption attaches to USDA pronouncements under FMIA regardless of their administrative pedigree. In *Grocery Manufacturers of America, Inc. v. Gerace,* the Court of Appeals upheld the preemptive effect of USDA's adoption of Food and Drug Administration ("FDA") rules for "imitation" labeling:

> Even if [USDA's action] should be classified as an interpretive rule or a statement of general policy. . . we discern no reason to reject the USDA's longstanding interpretation of [FMIA].

1991) (state subjective inspection procedures that differed from objective federal standards held preempted by FMIA); *Meat Trade Institute, Inc. v. McLaughlin,* 326 N.Y.S.2d 683, 685 (N.Y.A.D. 1971) (higher city meat standard preempted).

See also National Broiler Council v. Voss, 44 F.3d 740, 745 (9th Cir. 1994) ("The provision authorizes states to undertake. . .efforts to enforce *federal* requirements. It does not grant states the authority to enact their own additional requirements") (interpreting identical language of Poultry Products Inspection Act, 21 U.S.C. §467e) (emphasis original); *Northwestern Selecta, Inc. v. Munoz,* 106 F. Supp. 2d 223, 233 (D.P.R. 2000) (preemption under Poultry Products Inspection Act).

6. *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.,* 626 F. Supp. 278, 285-86 (D. Mass.) (consumer fraud claim concerning sub-therapeutic antibiotics preempted), *aff'd without op.,* 802 F.2d 440 (1st Cir. 1986); *Mario's Butcher Shop & Food Center, Inc. v. Armour & Co.,* 574 F. Supp. 653, 656 (N.D. Ill. 1983) ("no liability may be found where the product complies with federal regulations"); *Boulahanis v. Prevo's Family Market, Inc.,* 583 N.W.2d 509, 512 (Mich. App. 1998) ("any state tort action based on a theory that adulterated meat was distributed must therefore be based on standards that are identical to federal standards"), *appeal denied sub nom. Sowerby v. Prevo's Family Market, Inc.,* 591 N.W.2d 38 (Mich. 1999), *cert. denied,* 530 U.S. 1203 (2000); *Kircos v. Holiday Food Center, Inc.,* 477 N.W.2d 130, 131-32 (Mich. App. 1991) (state-law negligence per se action preempted where meat "is not 'adulterated' under the federal act"), *appeal denied,* 487 N.W.2d 412 (Mich. 1992).

755 F.2d 993, 1002 (2d Cir. 1985). When the affected state appealed that decision as of right, this Court summarily affirmed the finding of preemption. *Gerace v. Grocery Manufacturers of America, Inc.*, 474 U.S. 801 (1985).[7]

Under existing law, preemption flowed as a matter of course so long as USDA's determination that Petitioner's meat was not "adulterated" controlled. To avoid preemption required the Wisconsin court to make an extreme and unprecedented ruling – that reference to agency discretion in one subsection of §601(m) impliedly divested USDA of authority to construe every subsection that did not mention discretion.

This ruling has no precedent, and finds no support in FMIA's legislative history. The legislative history of the amendments that added the language at issue states that the "judgment of the Secretary" clause in §601(m)(2)(A) was to "give the Secretary of Agriculture *more* discretion" and "to allow the Secretary. . .to impose *more* stringent restrictions" under that subsection. S. Rep. No. 799 (1967), *reprinted in,* 1967 U.S.C.C.A.N. 2188, 2195 (emphasis added). Nowhere in the legislative history is any suggestion that this amendment was intended to reduce administrative discretion. Where Congress intended to restrict USDA discretion, it said so explicitly. *See id.,* 1967 U.S.C.C.A.N. at 2197 ("[r]emoving the Secretary's discretion" concerning *ante mortem* inspections).

By striking at FMIA itself, the Wisconsin court left a far more extensive tear in the fabric of national uniformity than merely leaving a few non-conforming tort claims unpreempted. The court nullified in Wisconsin USDA's discretionary power to define "adulteration." Anyone in Wisconsin – state agencies as well as private plaintiffs – may now ignore USDA's interpretation. The court's rationale for

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7. The manufacturers sought review of other issues, but their petition for *certiorari* was denied. *Grocery Manufacturers of America, Inc. v. Gerace,* 474 U.S. 820 (1985).

constricting federal administrative discretion is equally applicable to any federal agency or statute.

II. THE HOLDING THAT USDA WAS IMPLIEDLY DIVESTED OF ITS ADMINISTRATIVE DISCRETION WILL DISRUPT ADMINISTRATION OF OTHER FEDERAL STATUTES.

The Wisconsin court gave no effect to Congress' general delegation of regulatory authority in 21 U.S.C. §621. Solely analyzing 21 U.S.C. §601(m), that court found only "focused" delegation because just one of nine definitions of "adulterated" expressly mentioned USDA discretion (Pet. App. 12a ¶10). For the other eight definitions, the court held that "Congress has itself...defined 'adulterated' without seeking the Secretary's input" (Pet. App. 19a ¶20). Congressional silence rendered USDA "powerless" to interpret those definitions in any way. *Id.*

Many federal statutes regulate products made by PLAC members. Like FMIA, these statutes include multiple definitions or other subsections that inconsistently reference administrative discretion. To demand explicit congressional reaffirmation of such discretion – on a subsection-by-subsection level – would have far reaching effects upon federal regulation of many products.

A. The Ruling Implicates Federal Regulation Of Food, Drugs, Medical Devices, and Cosmetics.

Besides FMIA, the statute most affected by the Wisconsin court's decision is the Food, Drug & Cosmetic Act, 21 U.S.C. §§301, *et seq.* ("FDCA"). Congress expressly

intended FMIA to track FDCA.[8] In particular, FMIA's "adulteration" and "misbranding" provisions, §§601(m-n), parallel FDCA definitions of those terms for food. *See* 21 U.S.C. §§342-43. Since FMIA's enactment, USDA has continued to adopt FDA standards without significant change. *Grocery Manufacturers,* 755 F.2d at 1002 (discussing "USDA's practice of following the FDA definition").

FDA regulations of prescription medical products would also be affected. If the Wisconsin court's rationale were extended to the equivalent definition of "adulterated" in 21 U.S.C. §351(a),[9] FDA would retroactively lose the authority to interpret for all drugs and medical devices:

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8. The definitions of "adulterated" and "misbranded" in FMIA were expressly "based on the definition[s] of the same term[s] in the Federal Food, Drug, and Cosmetic Act and [are] identical except" for certain changes that Congress specified. S. Rep. No. 799 (1967), *reprinted in,* 1967 U.S.C.C.A.N. at 2194 & 2195. The acts FMIA prohibits are "generally comparable" to acts prohibited by FDCA. *Id.,* at 2199.

9. Section 351(a) states, in pertinent part, that a drug or medical device is "adulterated":

"(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. . .; or (C) if it is a compounded positron emission tomography drug and. . .do[es] not conform to or [is] not operated or administered in conformity with the positron emission tomography compounding standards. . .; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of §379e(a) of this title, or (B) it is a color additive. . .and is unsafe within the meaning of §379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of §360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of §360b of this title."

- what is "filthy, putrid or decomposed," under subsection (1);
- what are "insanitary conditions" and "contaminated with filth," under subsection (2)(A);
- what is "good manufacturing practice" under subsection (2)(B); and
- what are "poisonous or deleterious substance[s]" that cannot be used in containers under subsection (3).

This result would occur because, unlike other parts of §351(a),[10] these subsections neither mention nor reference FDA discretion. Under the Wisconsin court's rationale, FDA could enforce FDCA adulteration standards for color additives and animal feed, but states could override FDA good manufacturing practice for drugs and medical devices.[11]

The adulteration provisions of 21 U.S.C. §351 are only the most directly comparable FDCA analogue. Section 352, pertaining to misbranding, contains eighteen subsections, including five that make no express mention of FDA discretion.[12] The Wisconsin court would thus deny effect to FDA interpretation of these subsections. Similarly, 21 U.S.C. §321 defines numerous substantive terms for the

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10. Subsections (4-6) of this section have cross-references to other FDCA sections that explicitly recognize FDA discretion.

11. *See* 21 C.F.R. Parts 210-11. Statutes are simply not drafted with the precision demanded by the Wisconsin court's focus on subsection-level references to administrative discretion. While §351(a)(2)(B) neither mentions nor references FDA discretion concerning "good manufacturing practice," another section of FDCA expressly grants such discretion — but only for medical devices, not drugs. *See* 21 U.S.C. §360j(f).

12. The subsections of 21 U.S.C. §352 lacking express language are: (a) "False or misleading label," (c) "Prominence of information on label," (i) "Drug; misleading container; imitation; offer for sale under another name," (j) "Health-endangering when used as prescribed," and (s) "Devices subject to performance standards not bearing requisite labeling."

entire statute. Seventeen of these definitions – including such basic terms as "food," "drug," and "cosmetic" – contain no express grant of discretion to FDA.[13] There are numerous other FDCA subsections potentially subject to the same objection that the Wisconsin court interposed here.[14]

B. The Ruling Implicates Federal Regulation Of Motor Vehicles.

Production of on-road motor vehicles (cars, trucks, motorcycles, *etc.*) is regulated by the National Traffic & Motor Vehicle Safety Act of 1966, 49 U.S.C. §§30101, *et seq.* ("Safety Act"). The Safety Act not only has a general grant of administrative discretion, 49 U.S.C. §30111(a), but also contains many subsection-level references to such discretion.

Such references appear initially in the Safety Act's two sets of definitions. 49 U.S.C. §30102 (a-b). None of the definitions in subsection (a) reference administrative discretion,[15] but subsection (b) ("limited definitions"[16]) contains a provision specifically recognizing such discretion.

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13. *See* 21 U.S.C. §321(f) ("food"); (g)(1) ("drug"); (g)(2) ("counterfeit drug"); (h) ("device"); (i) ("cosmetic"); (j) ("official compendium"); (l) ("immediate container"); (m) ("labeling"); (p) ("new drug"); (r) ("raw agricultural commodity"); (u) ("safe"); (w) ("animal feed"); (y) ("saccharin"); (z) ("infant formula"); (gg) ("processed food"); (ii) ("compounded positron emission tomography drug"); (jj) ("antibiotic drug"). Other definitions do expressly acknowledge FDA discretion. *See* 21 U.S.C. §321(k) ("label"); (q) ("pesticide chemical"); (s) ("food additive"); (t) ("color additive"); (v) ("new animal drug"); (ff) ("dietary supplement").

14. Other FDCA provisions, the subdivisions of which do not uniformly recognize FDA discretion, are: 21 U.S.C. §331 ("prohibited acts"); §333 ("penalties"); §342 ("adulterated food"); and §343 ("misbranded food").

15. These definitions include "defect," "manufacturer," "motor vehicle," and "motor vehicle safety." *See* 49 U.S.C. §§30102(a)(2, 5-6, 8).

16. These definitions include "adequate repair," "first purchaser," "original equipment," and "replacement equipment." 49 U.S.C. §§30102(b)(1)(A-D).

See 49 U.S.C. §30102(b)(2). Under the Wisconsin court's reasoning that specific mention of discretion in one subsection excludes discretion elsewhere, the National Highway Traffic Safety Administration ("NHTSA") would lose power to issue binding interpretations of the definitions in §30102(a).

Certain categories of vehicles are excluded from Safety Act regulation by 49 U.S.C. §30112(b). Of nine exceptions, only one specifically references agency discretion.[17] Courts, the legislature, or administrative agencies in Wisconsin could thus ignore NHTSA's reading of the scope of the other eight exceptions and require otherwise exempt vehicles to meet Safety Act standards. Safety Act remedies are also implicated. The statute expressly authorizes NHTSA to promulgate regulations concerning repair or replacement of defective vehicles, 49 U.S.C. §30120(a)(2), but is silent about remedies for defective tires. *Id.* §30120(b).

If the Wisconsin court's opinion stands, federal ability to administer performance and safety standards applicable to more than 10 million motor vehicles sold annually in the United States could be severely degraded.

C. The Ruling Implicates Federal Regulation Of Consumer Products.

The Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§2051, *et seq.*, charges the federal Consumer Product Safety Commission ("CPSC") with responsibility to set safety standards for a host of products, from cigarette lighters to amusement park rides. Like FMIA, CPSA contains a general grant of administrative discretion. 15 U.S.C. §2056(a). If the Wisconsin court's rationale were applied to CPSA, it would likewise have disruptive effects.

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17. That exception reads: "a motor vehicle the Secretary of Transportation decides. . .is capable of complying with applicable standards under this chapter." 49 U.S.C. §30112(b)(4). This exception applies to imported automobiles. *See id.* §§30141-45.

CPSA §2052 contains definitions applicable to the entire statute. Some of these definitions reference agency discretion or agency rulemaking,[18] but most do not.[19] Under the negative implication rule of the Wisconsin court, CPSC would lose discretion to interpret most of the operative definitions that govern its actions.

Similar situations exist in substantive portions of CPSA. For example, 15 U.S.C. §2064, "Substantial product hazards" expressly references discretionary CPSC orders in subsections (b-d), (e)(2) and (g) – but not in subsections (a) (defining "substantial product hazard") and (e)(1) (authorizing reimbursement orders). If the Wisconsin decision extends to CPSA, CPSC cannot enforce its interpretations of the very hazards it is charged with preventing.[20]

The decision in this case uniquely threatens the entire range of federal uniform nationwide product safety standards. For this reason, the Court should grant the Petition.

III. THE WISCONSIN COURT'S REFUSAL TO GIVE ANY DEFERENCE TO USDA'S ACTION CONFLICTS WITH THIS COURT'S DECISIONS.

Almost as stunning as denying USDA discretion to interpret FMIA §601(m) is the Wisconsin court's next step. The court put its own gloss on §601(m), giving USDA

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18. Definitions expressly referencing the administrative authority or rules include: §2052(a)(1) (defining "consumer product"); and (a)(2) (defining "consumer product safety rule").

19. Definitions in §2052(a) lacking reference to administrative discretion include: (3) ("risk of injury"); (4) ("manufacturer"); (5) ("distributor"); (6) ("retailer"); (7) ("private labler"); (8) ("manufactured"); (11) ("distribute in commerce"); and (12) ("commerce").

20. Similar implied divestiture of administrative discretion could occur under the rationale of the Wisconsin court with respect to the Federal Insecticide, Fungicide, Rodenticide Act. *See* 7 U.S.C. §§136 ("definitions"); 136j ("unlawful acts").

decisions no deference. On the same administrative record, *see* (Pet. App. 21a-27a ¶¶23-26), the court struck a radically different balance than USDA. It essentially disregarded the factor USDA found most compelling – that ordinary cooking routinely eliminates health risks from *E. coli* and other bacteria.[21] Instead, the court recast USDA's "goal" of "zero tolerance" for visible digestive matter into "zero tolerance" for bacteria and interpreted §601(m) to require bacteria be "reduc[ed] to an undetectable level," regardless of other considerations. *See* (Pet. at 10 n.2) (Pet. App. 26a, 31a ¶¶25, 34).

This cavalier disregard of USDA decisions and creation of a novel, Wisconsin-specific definition of "adulterated" should be barred by the deference accorded administrative action. Deference is particularly needed where, as here, a state court reviews federal action. The Wisconsin court's holding is contrary to well-settled deference principles under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), and subsequent cases.

A. This Court's Decisions Require Deference Be Given To The USDA Action In This Case.

When an agency interprets its own organic statute, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction." *Chevron*, 467 U.S. at 843. *Chevron* analysis is thus bifold: (1) does the statute speak to the precise question, and (2) if not, is the agency's interpretation permissible. *Id.* at 842-43; *Food & Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000). Here, FMIA's multiple definitions of "adulterated" are unclear as to bacteria generally and

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21. *E.g., Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143, 145-49 (W.D. Tex. 1994); 67 Fed. Reg. 62,325, 62,326 (Oct. 7, 2002), 64 Fed. Reg. 2803, 2804 (Jan. 19, 1999); 60 Fed. Reg. 6774, 6799 (Feb. 3, 1995); *see also American Public Health Ass'n v. Butz*, 511 F.2d 331, 332 (D.C. Cir. 1974) (cooking kills salmonella; no need for microscopic examination).

silent on both *E. coli* and "intact" meat. Therefore, the Wisconsin court should not have ignored USDA's decision.

USDA's decision, while an interpretive rule rather than a formal regulation, appeared three times in the Federal Register, and was judicially reviewed. *See, supra,* at n.21. *Chevron* deference is not premised upon notice and comment rulemaking. *Edelman v. Lynchburg College,* 535 U.S. 106, 114 (2002) (*Chevron* "does not necessarily require . . .express notice-and-comment rulemaking"); *United States v. Mead Corp.,* 533 U.S. 218, 230-31 (2001) ("reasons for *Chevron* deference even when no such administrative formality was required and none was afforded"); *Young v. Community Nutrition Institute,* 476 U.S. 974, 981-83 (1986) (informally adopted FDA "action levels" given *Chevron* deference). Earlier this Term, the Court gave a "measure of respect" to agency guidance memoranda that had not even been published in the Federal Register. *Alaska Dep't of Environmental Conservation v. EPA,* ___ U.S. ___, 124 S. Ct. 983, 1001 (2004) ("*ADEC*"). Agency action qualifies for *Chevron* deference "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Mead Corp.,* 533 U.S. at 226-27.

USDA's interpretation deserves *Chevron* deference under *ADEC* and *Mead.* Congress delegated authority to USDA in 21 U.S.C. §621. USDA actions under its delegated authority carry force of law, as evidenced by sanctions for noncompliance. *See,* 21 U.S.C. §§676 (criminal penalties); 673 (seizure/condemnation). Under this Court's precedents, the Wisconsin court was obligated to defer to USDA's permissible interpretation of "adulterated."

B. Did Congress Address The Precise Question?

Deciding if Congress specifically addressed the question requires review of the entire statute – not, as here, isolated subsections. *Brown & Williamson,* 529 U.S. at 132. "[W]ords

of a statute must be read in their context and with a view to their place in the overall statutory scheme," with "all parts" fitting, if possible "into an harmonious whole." *Id.* at 132-33 (citations omitted). *See also Brown v. Gardner,* 513 U.S. 115, 118 (1994) ("[a]mbiguity is a creature not of definitional possibilities but of statutory context"). Implicit in statutory ambiguity is delegation to the agency to fill such gaps, and courts are not to substitute their readings for reasonable agency interpretations. *Chevron,* 467 U.S. at 844.

Congress did not address in FMIA when live bacteria would make fresh meat "adulterated." Definitions of "adulterated" are purposely vague, keeping them dynamic. Inclusion of all adulterating circumstances in FMIA would doom it to obsolescence. USDA now considers as adulterants substances that were not so thought – or were entirely unknown[22] – in 1967 when §601(m) was amended.

That the Wisconsin court's holding is so profoundly in conflict with USDA's construction of "adulterated" itself indicates statutory ambiguity. *Smiley v. Citibank (South Dakota), N. A.,* 517 U.S. 735, 739 (1996) ("difficult indeed" not to find ambiguity given "the conflict that has prompted us to take this case") (footnote omitted).[23] Further, by considering only the discretion mentioned in 21 U.S.C. §601(m)(2)(A), to the exclusion of FMIA's general delegation

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22. *E. Coli* 0157:H7 was first discovered in 1975 and not identified as a human pathogen until 1982. *See* < http://vm.cfsan.fda.gov/~mow/fdacook.html > (visited Feb. 10, 2004) (FDA Medical Bulletin (June 1993)). Similarly, only in 1992 were misshapen proteins called prions confirmed as causing "mad cow" disease (bovine spongiform encephalopathy). *See* < http://www.nobel.se/medicine/laureates/1997/press.html > (visited Feb. 6, 2004) (official announcement of award of 1997 Nobel Prize in Medicine to Dr. Stanley B. Prusiner for discovery of prions).

23. The holding here also conflicts with *American Public Health Ass'n v. Butz,* 511 F.2d at 334 (salmonella not an "adulterant" under §601(m)); and *Texas Food Industry Ass'n,* 870 F. Supp. at 145-49 (USDA properly declared *E. coli* an "adulterant").

to USDA,[24] the court violated this Court's command to treat the statute as a whole. *Brown & Williamson,* 529 U.S. at 132-33. The express congressional delegation in §621 is an excellent indicator that USDA's decision here deserves deference under *Chevron. Mead Corp.,* 533 U.S. at 231.

C. Was USDA's Interpretation Permissible?

Courts must defer to agency interpretations that reflect permissible statutory constructions. *Chevron,* 467 U.S. at 843. Having improperly held FMIA's definitions of "adulterated" to be unambiguous, the Wisconsin court never addressed the permissibility of USDA's decision that "intact" meat with only surface *E. coli* was not adulterated.

Congress "underst[ands] that [statutory] ambiguity would be resolved, first and foremost, by the agency, and desire[s] the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows." *Smiley,* 517 U.S. at 740-41 (citation omitted). Deference is required: (1) because "responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," *Chevron,* 467 U.S. at 866; and (2) due to "the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated." *Brown & Williamson,* 529 U.S. at 132 (citation omitted). An agency construction need not be the only possible outcome – only "sufficiently rational. . .to preclude a court from substituting its judgment for that of [the agency]." *Young,* 476 U.S. at 981 (citations omitted).

USDA's recognition that surface *E. coli* die when cooked, 64 Fed. Reg. at 2804, justifies its conclusion that

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24. "[S]aid Secretary shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter." 21 U.S.C. §621.

the meat at issue is not "adulterated."[25] Meat is "ordinarily" cooked before it is eaten, so surface bacteria no longer "render it injurious to health." 21 U.S.C. §601(m)(1). By contrast, the Wisconsin court's decision is unfairly retroactive. Not only is the "goal" of "zero tolerance" (Pet. App. 26a, 31a) misconstrued, *see, supra,* at 13, it came from a policy statement issued in October, 2002[26] – more than two years after the July 2000 incident alleged in the complaint.

IV. INVALIDATION OF USDA'S DISCRETIONARY STATUTORY INTERPRETATION IMPLICATES FMIA'S CONSTITUTIONALITY.

If USDA cannot clarify broad statutory terms such as "poisonous," "deleterious," "filthy," "putrid," and "insanitary," §601(m) may become unconstitutionally vague. This Court has held statutes "void for vagueness if [their] prohibitions are not clearly defined." *Grayned v. Rockford,* 408 U.S. 104, 108 (1972). First, the law must "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited." *Id.* Second, to prevent arbitrary or discriminatory enforcement, "laws must provide explicit standards for those who apply them." *Id.* Vague laws

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25. This conclusion followed exhaustive fact finding by USDA's Food Safety & Inspection Service ("FSIS"). FSIS is a sponsor of the National Advisory Committee on Microbiological Criteria for Foods, the entity Congress has charged with conducting scientific studies and surveillance concerning food. *See* 68 Fed. Reg. 46,569, 46,569-70 (Aug. 6, 2003) (describing Committee). Federal Register entries concerning the *E. coli* policies at issue detail the dozens of epidemiological studies and other scientific resources FSIS utilized. *See* 67 Fed. Reg. at 62,326-27 & nn.3-19; 65 Fed. Reg. 6881, 6883 (Feb. 11, 2000); 64 Fed. Reg. at 2804-05; 60 Fed. Reg. at 6781-84, *see also id.* at 6834-37, 6852-53, 6854-55 (220 listed references, 20 mentioning the *E. coli* bacterium in their titles).

26. Pet. App. 26a, 31a (citing 67 Fed. Reg. at 62,329).

impermissibly give "basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis." *Id.* at 109.[27]

The effect of the Wisconsin court's decision is to wipe away USDA administrative interpretations that import necessary structure to FMIA. The court's strait-jacketed interpretation admits neither nuance nor practicality. Meat suppliers could now be criminally sanctioned for "adulterated" meat, based on nothing more than the all-encompassing FMIA definition. With no limiting principle, a Wisconsin declaration of *per se* adulteration because all potentially harmful bacteria must be "undetectable" (Pet. App. 26a ¶26) in tests not required by any statute or regulation, would be the sort of "*ad hoc* and subjective" ruling condemned as unconstitutionally vague in *Grayned, supra.*[28]

FMIA's adulteration definitions track FDCA and other federal statutes, against which void-for-vagueness challenges have failed in light of ample administrative guidance. "The Secretary's interpretive regulations. . .concretize the statutory language [and] eliminate the possibility of vagueness."[29] Conversely, vagueness challenges to such definitions have succeeded where "the language of the

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27. *See also, e.g., Smith v. Goguen,* 415 U.S. 566, 575-76 (1974); *Papachristou v. City of Jacksonville,* 405 U.S. 156, 162 (1972).

28. As Petitioner points out (Pet. at 8), all raw meat naturally contains bacteria, and bacteria such as *E. coli* and salmonella can hurt people eating improperly prepared meat. The Wisconsin court's holding that such bacteria, regardless of circumstances, are "deleterious substance[s that] may render [meat] injurious to health" under §601(m)(1) potentially declares all raw meat "adulterated."

29. *United States v. Articles of Drug Labeled Colchicine,* 442 F. Supp. 1236, 1241 (S.D.N.Y. 1978) (citations omitted); *see, e.g., United States v. Sullivan,* 332 U.S. 689, 694 (1948); *United States v. Jamieson-McKames Pharmaceuticals, Inc.,* 651 F.2d 532, 545 n.24 (8th Cir. 1981); *United States v. Article of Drug Labeled "White Quadrisect,"* 484 F.2d 748, 749 (7th Cir. 1973); *United States v. Bel-Mar Laboratories, Inc.,* 284 F.Supp. 875, 883 (E.D.N.Y. 1968).

statute, [is] unclarified by appropriate regulations of the Secretary."[30] Wisconsin is no longer bound by USDA's clarifying regulations.

It is irresponsible to expose broad federal statutes essential to public health to vagueness charges by divesting administrative agencies of long-standing discretion to interpret and clarify their language. Vagueness challenges arise in criminal cases. They give comfort to serious violators and place responsible businesses that comply with existing regulations at competitive disadvantage. This Court should not permit such unnecessary disruption of federal regulation.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

Of Counsel:
HUGH F. YOUNG, JR.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 22091
(703) 264-5300

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JAMES M. BECK*
EDWARD T. FISHER
DECHERT LLP
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103-2973
(215) 994-2970
Attorneys for Product Liability Advisory Council, Inc.

* *Counsel of Record*

30. *United States v. Fabro, Inc.*, 206 F. Supp. 523, 526 (M.D. Ga. 1962); *see also, United States v. 2,116 Boxes of Boned Beef*, 516 F. Supp. 321, 344-45 (D. Kan. 1981), *aff'd*, 726 F.2d 1481 (10th Cir.), *cert. denied*, 469 U.S. 825 (1984).

APPENDIX

APPENDIX

PRODUCT LIABILITY ADVISORY COUNCIL, INC. CORPORATE MEMBERS

3M
Altec Industries
Altria Corporate Services, Inc.
American Household, Inc.
American Suzuki Motor Corporation
Amgen Inc.
Andersen Corporation
Anheuser-Busch Companies
Appleton Papers, Inc.
Astec Industries
Aventis Pharmaceuticals, Inc.
BASF Corporation
Baxter International, Inc.
Bayer Corporation
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone/Firestone, Inc.
Briggs & Stratton Corporation
Bristol-Myers Squibb Company
Brown and Williamson Tobacco
Brown-Forman Corporation
CARQUEST Corporation
Caterpillar Inc.
CCA Industries, Inc.
Chevron Corporation
Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation
DaimlerChrysler Corporation
Dana Corporation
Deere & Company
Delphi Corporation
Dorel Juvenile Group, Inc.
Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Federal Signal Corporation
FMC Corporation
Ford Motor Company
Freightliner LLC
General Electric Company
General Motors Corporation
Georgia-Pacific Corporation
GlaxoSmithKline
GLOCK, Inc.
Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Guidant Corporation

Harley-Davidson Motor Company
Harsco Corporation
Heil Company
Honda North America, Inc.
Hyundai Motor America
ICON Health & Fitness, Inc.
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Johnson & Johnson
Johnson Controls, Inc.
Joy Global Inc., Joy Mining Machinery
Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Kolcraft Enterprises, Inc.
Kraft Foods North America, Inc.
Lincoln Electric Company
Masco Corporation
Mazda (North America), Inc.
McNeilus Truck and Manufacturing, Inc.
Medtronic, Inc.
Mercedes-Benz of North America, Inc.
Michelin North America, Inc.
Miller Brewing Company
Niro Inc.
Nissan North America, Inc.
Novartis Pharmaceuticals Corporation
PACCAR Inc
Panasonic
Pentair, Inc.
Pfizer Inc.
Pharmacia Corporation
Polaris Industries, Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Procter & Gamble Company
Purdue Pharma L.P.
Raymond Corporation
Raytheon Aircraft Company
Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Schering Corporation
Schindler Elevator Corporation
SCM Group USA Inc.
Sears, Roebuck and Co.
Shell Oil Company
Sherwin-Williams Company
Smith & Nephew, Inc.
Snap-on Incorporated
Sofamor Danek, Medtronic Inc.
Solutia Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
Thomas Built Buses, Inc.
TK Holdings
Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive US LLC
UST (U.S. Tobacco)
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Water Bonnet Manufacturing, Inc.
Whirlpool Corporation
Wilbur-Ellis Company
Wyeth
Yamaha Motor Corporation, U.S.A.
Zimmer, Inc.